Perspectives on Essential Health Benefits: Workshop Report

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Perspectives on Essential Health Benefits

WORKSHOP REPORT

Cheryl Ulmer, Bernadette McFadden, and Cassandra Cacace, *Rapporteurs*

Committee on Defining and Revising an Essential Health Benefits Package for Qualified Health Plans

Board on Health Care Services

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Willing is not enough; we must do."
—Goethe

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[1] The report summarizes the views expressed by workshop participants, and while the committee is responsible for the overall quality and accuracy of the report as a record of what transpired at the workshop, the views contained in the report are not necessarily those of the committee.

Reviewers

This report has been reviewed in draft form by individuals chosen for their diverse perspectives and technical expertise, in accordance with procedures approved by the National Research Council's Report Review Committee. The purpose of this independent review is to provide candid and critical comments that will assist the institution in making its published report as sound as possible and to ensure that the report meets institutional standards for objectivity, evidence, and responsiveness to the study charge. The review comments and draft manuscript remain confidential to protect the integrity of the process. We wish to thank the following individuals for their review of this report:

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SARA ROSENBAUM, Professor and Chair, Department of Health Policy, George Washington University School of Public Health and Health Services

Although the reviewers listed above have provided constructive comments and suggestions, they were not asked to endorse the final draft of the report before its release. The review of this report was overseen by **CHRISTINE K. CASSEL,** American Board of Internal Medicine. Appointed by the Institute of Medicine, she was responsible for making certain that an independent examination of this report was carried out in accordance with institutional procedures and that all review comments were carefully considered. Responsibility for the final content of this report rests entirely with the authors and the institution.

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Summary

The Patient Protection and Affordable Care Act (ACA),[1] which was signed into law on March 23, 2010, requires all individuals to purchase health insurance beginning in 2014. Purchasers are allowed but not obliged to buy their coverage through newly established health insurance exchanges—marketplaces designed to make it easier for customers to comparison shop among plans. The exchanges will offer a choice of health plans, and all plans must include a standard core set of covered benefits, called essential health benefits (EHB). Additionally, the EHB are required to be included in new private individual and small group health insurance plans offered outside of the exchanges, and in certain public insurance programs. Subsidies will only be available through the exchanges, and then on the basis of a sliding scale for individuals whose incomes are between 133 and 400 percent of the federal poverty level.[2]

Section 1302 of the ACA stipulates that the Secretary of the U.S. Department of Health and Human Services (HHS) is to define the EHB (Appendix A). The EHB must include at least 10 general categories of care and be equal in scope to those offered by a typical employer plan. The health insurance exchanges will only offer qualified health plans (QHPs), meaning the plans are deemed to cover the EHB and to meet other requirements set by the ACA.

CHARGE TO THE COMMITTEE

HHS requested guidance from the Institute of Medicine (IOM) on criteria and methods for determining and updating the EHB package to help the Secretary in carrying out the responsibilities assigned under ACA. Accordingly, the IOM formed the Committee on Defining and Revising an Essential Health Benefits Package for Qualified Health Plans to undertake the task described in Box S-1. The committee began its work by affording the public opportunities for comment through two venues. First, through online submission of comments to a set of relevant questions (Appendix B) and through invitations to present at public workshops held on January 13-14, 2011, in Washington, DC, and on March 2, 2011, in Costa Mesa, California.

During these workshops, many stakeholders (e.g., experts from federal and state government, employers,

1 Patient Protection and Affordable Care Act of 2010 as amended. Public Law 111-148, 111th Cong., 2d sess. (See http://docs.house.gov/energycommerce/ppacacon.pdf as amended through May 1, 2010; all references to the Act reflect this version.)

2 Individuals whose incomes are below 133 percent of the federal poverty level will be eligible for Medicaid, and the EHB do not apply to the traditional Medicaid program, although they are applicable to state expansions of insurance for low income individuals, called Medicaid benchmark or benchmark equivalent plans, and state basic health insurance (§ 2001 and § 1331).

BOX S-1
Statement of Task for the IOM Committee

The Patient Protection and Affordable Care Act (Affordable Care Act) established criteria for qualified health plans (QHPs) to participate in exchanges as defined in Section 1301 of the statute. An ad hoc IOM committee will make recommendations on the methods for determining and updating essential health benefits for QHPs based on examination of the subject matter below.

In so doing, the committee will identify the criteria and policy foundations for determination of the essential health benefits offered by QHPs taking into account benefits as described in Sections 1302(b)(1) and 1302(b)(2)(A), and the committee will assess the methods used by insurers currently to determine medical necessity and will provide guidance on the "required elements for consideration" taking into account those outlined in Section 1302(b)(4)(A-G), including ensuring appropriate balance among the categories of care covered by the essential health benefits, accounting for the health care needs of diverse segments of the population, and preventing discrimination against age, disability, or expected length of life. The committee will also take into account language in Section 1302 on periodic review of essential health benefits, and other sections of the Affordable Care Act: for example, coverage of preventive health services (Section 2713), utilization of uniform explanation of coverage documents and standardized definitions (Section 2715), and other relevant tasks found in the Affordable Care Act for the Secretary of HHS. The committee will provide an opportunity for public comment on the tasks of defining and revising the essential health benefits.

insurers, health care providers, consumers, and health care researchers) contributed to the policy debate; their presentations are the subject of this summary report. This report only contains the summaries of presentations from the two workshops, which were just one aspect of the committee's information gathering steps. Thus, the workshop report is not intended to provide recommendations in response to the statement of task.

To explain HHS's expectations of the committee, Dr. Sherry Glied, the Assistant Secretary for Planning and Evaluation and the study sponsor, remarked at the first workshop that we do not expect this committee "to identify the individual elements or the detailed provisions" of the EHB package. Instead, she asked the committee to develop a framework for considering the EHB package "that will be logically cohesive, address statutory requirements, and serve HHS now and in the future."

KEY ISSUES

Over the course of the workshops, participants noted many potential implications of the definition of the EHB, recognizing both the promise and challenges that lie ahead. Discussion of the committee's charge coalesced around the following topics, including:

- Balancing the generosity of coverage with affordability of insurance products;
- Defining a "typical" employer plan;
- Evaluating existing state mandates for inclusion into the EHB;
- Considering the degree of specificity versus flexibility in forthcoming secretarial guidance;
- Determining the medical necessity of care;
- Promoting value in benefit design;
- Applying evidence to benefit coverage;
- Monitoring Section 1302's "required elements for consideration";
- Instituting an appeals process as a safeguard; and
- Ensuring fair processes.

This summary chapter of the workshop report presents illustrative comments of different viewpoints according to key themes raised. The chapters that follow more fully capture the statements of all of the presenters; speakers were given the opportunity to review the summary of their individual presentations for the chapters before publication. Any conclusions, recommendations, or supporting documentation offered in this publication are those of the speakers and not the IOM committee, whose own consensus recommendations are featured in a companion report called *Essential Health Benefits: Balancing Coverage and Cost*.

BALANCING GENEROSITY AND AFFORDABILITY

Numerous speakers noted the clear tension between the desire to make the EHB package as comprehensive as possible and the need to make the EHB package affordable for individuals, families, employers, states, and the federal government. Dr. Louis Jacques, director of the Coverage & Analysis Group at the Centers for Medicare & Medicaid Services, advised the committee to balance the competing needs of generosity and affordability, but to resist the temptation to bend to the demands of influential stakeholder groups.

Presentations by a bipartisan panel of former and current Senate staff members noted that Congress wanted the legislation to have general benefit descriptions, preferring that details be worked out during implementation. That said, the panelists expressed some disagreement about what the ultimate package would look like—whether the desire was to create a "robust" benefit package vs. a "minimum" benefit package. Mr. David Schwartz said that Congress intended the EHB package to be "meaningful" and comprehensive and thus, linked it to the benefits of a typical large employer plan. Echoing Mr. Schwartz's comment, Dr. David Bowen said that the Senate did not intend for the EHB package to be a "skimpy plan" but one covering "at least" 10 categories of care. In contrast, Mr. Mark Hayes similarly pointed out that the ACA uses the term essential because the legislature intended these to be basic not comprehensive benefits. Moreover, Ms. Katy Spangler emphasized that the committee should "look at the least robust version of the benefit package as meeting" the standard of minimum essential coverage; otherwise, she said, fewer people will be able to afford coverage thus defeating the purpose of ACA to expand coverage.

Other presenters drew on their experiences with performing microsimulations and real world tradeoffs of benefits and their costs. Dr. Jonathan Gruber of MIT, and on the board of the Massachusetts Health Insurance Connector Authority (an operational health insurance exchange), illustrated tradeoffs with what he called an extreme example from a microsimulation: a 10 percent increase in costs due to a more generous package would erode the effectiveness of the insurance mandate because an estimated 4.5 percent (approximately 1.5 million) fewer people would be insured. Dr. Jon Kingsdale, formerly executive director of the Connector Authority, said the ACA is "about giving more people decent coverage as opposed to being about raising the standard of coverage." He advised HHS, therefore, that when it has to "make decisions about close calls regarding benefits," it is important to remember that additional benefits are costly. Ms. Jean Fraser, the current chief of the San Mateo County Health System and the former CEO of the San Francisco Health Plan, discussed her experience "making hard choices" between coverage and cost when designing Healthy San Francisco, a public universal coverage program. To ensure stewardship of limited public resources, she made some "difficult decisions," resulting in a lengthy list of excluded services and a very narrow provider network. These limits, she said, allowed the program to affordably cover a "limited set of core services" for "most medical conditions for tens of thousands of people who did not have coverage before."

Employer groups and an insurance broker at the first workshop, including Ms. Jerry Malooley, a representative from the U.S. Chamber of Commerce; Mr. Michael Turpin from USI Insurance Services; and Ms. Helen Darling from the National Business Group on Health (NBGH), all expressed a strong desire to limit the comprehensiveness of the package. The more expansive the package, these panelists said, the greater the cost. Ms. Malooley cautioned that expansive benefits would likely force small employers to stop offering coverage, while Mr. Turpin noted that small and mid-size employers believe support for a "basic" level of benefits would help reduce cost growth.

Throughout the workshops, consumer and provider advocates, however, expressed their support and need for a robust, comprehensive plan. During a panel of presentations from 15 representatives of organizations spanning health care provider, pharmacy industry, and consumer perspectives, stakeholders advocated for an EHB package that encompasses a broad range of services, variously including coverage of medical, surgical, psychiatric,

rehabilitative, habilitative, dental, vision, primary and secondary preventive, palliative, pharmaceutical, and hospice services, among others. Along with these expressed desires, these stakeholders also often referenced the need for an affordable package, and the need for insurers and employers not to be short-sighted when it comes to evaluating the long-term value of a benefit offered today on future health outcomes.

The financial burden of premiums and other out-of-pocket medical costs can lead to persons having insurance but being underinsured. Dr. Jessica Banthin of the Agency for Healthcare Research and Quality and Ms. Cathy Schoen of The Commonwealth Fund explored this aspect of affordability. Dr. Banthin noted that in 2005, about 19 percent of the U.S. nonelderly population lived in families with high total out-of-pocket (OOP) financial burden (i.e., spending 10 percent or more of their income on OOP expenditures for health care) (Banthin, 2011). Ms. Schoen stressed that both uninsured and underinsured individuals are at high risk of foregoing needed care and of having financial stress related to outstanding medical bills or medical debt; her presentation also showed a significant portion of individuals with insurance forego care (31 percent) and have financial stress due to medical bills (21 percent). She credited some of this foregone care to the burden created by having plans with high deductibles.

DEFINING A "TYPICAL" EMPLOYER PLAN

Section 1302 of the ACA states that the scope of the essential health benefits should be "equal to the scope of benefits provided under a typical employer plan" and required the Secretary of Labor (DOL) to conduct a survey of employer-sponsored coverage. At the time of the January workshop, the DOL was in the "final stages of extracting and tabulating" data; its report was made available to HHS and the public in April 2011 (DOL, 2011). In lieu of that data, Mr. William Wiatrowski of the Bureau of Labor Statistics summarized data his department gathered in 2008:

- 99% of plan participants had coverage for hospital room and board charges
- 67% of plan participants had coverage for hospice care
- The median deductible was $500 per individual per year[3]
- The median co-payment for a physician office visit was $20 for a fee-for-service (FFS) plan and $15 for health maintenance organization (HMO)

Results, he said, showed considerable variation in the incidence[4] and cost of health benefits, based on worker and establishment characteristics (including occupational group, union status, full-time/part-time work schedule, industry, and employer size and location).

In response to an inquiry from committee member Dr. Elizabeth McGlynn, Dr. Glied of HHS noted that the committee's interpretation of the word "typical" would be useful. Paralleling the previous discussion of generosity and affordability, respondents associated large employer plans with more comprehensiveness and larger premiums. Dr. Bowen indicated that members of the Senate intended coverage to be consistent with a relatively generous large employer plan, whereas Dr. Virginia Calega from Highmark advocated that the committee consider small employer plans as "typical" because the definition of EHB will "primarily impact individual consumers, small businesses, and the self-employed."

Dr. Jeffrey Kang of CIGNA Corporation noted that the categories of care listed in the ACA are similar to the benefits offered by large employer plans either in standard plans or as supplements, with the exception of habilitation. However, Ms. Carmella Bocchino of America's Health Insurance Plans (AHIP) asserted that the ACA required maternity benefits, prescription drugs, and mental health coverage requires benefit categories not typically covered in the small group market. She said that consumers "choose to buy products without those services because: a) they do not feel the services meet their individual needs, and b) it helps to keep the premium down."

[3] In plans that impose an overall plan deductible (where the deductible varied based on the provider, the median was $350 for preferred providers and $750 for out-of-network providers).

[4] That is who has the health insurance available to them from their employer and what percentage of workers, who have it available, actually participate in the plan.

Dr. Kenneth Wells of UCLA emphasized how the Wellstone Domenici Mental Health Parity and Addiction Equity Act[5] "fundamentally changed the landscape" of what employers will cover regarding mental health and substance use treatment. Therefore, he felt it is necessary to look beyond what typical employer plans have covered in the past. Dr. Kavita Patel of UCLA elaborated that when health insurance expanded in Massachusetts, the newly insured included many individuals with mental health and substance use disorders, and these newly insured individuals tended to access mental health care by visiting the emergency room or community-based services, rather than private providers.

An additional consideration was brought forth by Ms. Carolyn Ingram, the former director of New Mexico's Medicaid, Children's Health Insurance Program, and a Medicaid expansion program for low-income workers. She suggested that HHS consider not only how the contents of a typical employer plan should influence essential health benefits but also those of traditional Medicaid and existing Medicaid expansions. She expressed concern that if the public and private packages differ substantially in benefits, people might not "want to migrate out of the Medicaid program and into the exchange."

EVALUATING STATE MANDATES FOR INCLUSION

The ACA allows states to require QHPs to offer benefits beyond the defined set of EHB as long as the state assumes the incremental costs of subsidies for the additional mandated benefits.[6] Mr. Hayes noted that the Senate Finance Committee included this provision because benefits that "make a lot of sense" for one state might not make "as much sense for other states." Presenters discussed what processes are used by states to assess the mandates and whether HHS should include state mandates in the EHB package.

Several presenters argued that state mandates are not evidence-based, contribute to increasing insurance premiums, and increase variability across states. Ms. Bocchino stated, for instance, that most state mandates have been enacted without an assessment of scientific evidence. Furthermore, it would be "almost impossible," she said, to include a large number of mandates in the EHB package or require individuals, small businesses, or states that do not currently have these mandates to incur the added cost. Similarly, Ms. Darling suggested that because state mandates are often driven "by forces that sometimes have very little to do with evidence and very little to do with cost considerations," the committee should not consider state mandates as a criterion for the EHB package.

Others argued for judgment based on the strength of evidence and/or consideration of popular support for mandates. For example, Mr. Stuart Spielman of Autism Speaks argued that HHS should view state mandates "as informed judgments of what is needed by populations," and Mr. John Falardeau of the American Chiropractic Association recommended that any benefit mandated in 25 or more states should be included in the EHB. Additional presenters, including Dr. Samuel Nussbaum of WellPoint, Inc., acknowledged that for mandates in which there is "absolute proof that something is beneficial," a "national coverage model" might help minimize state-by-state variation. Dr. Sharon Levine of the Permanente Medical Group agreed, but noted that states apply varying degrees of rigor in assessing evidence before mandating a benefit.

Determination of how much state mandates impact costs depends on the methodologies employed and the point of comparison—for example, whether presenters were discussing full or marginal costs, and if the comparison is to a comprehensive or slimmed down base plan. Drs. Beth Sammis of the Maryland Insurance Administration and Rex Cowdry of the Maryland Health Care Commission noted that Maryland has a mandate review process that calculates the full and the marginal costs of adding benefits. The full cost of Maryland's mandated benefits is 18.6 percent of average individual premiums and 15.4 percent of group premiums; however, the marginal cost of these state mandates is only approximately 2.2 percent because most of the mandated benefits are already voluntarily available in comparative self-funded plans that are exempt from mandates (MHCC, 2008). Ms. Malooley, on behalf of the U.S. Chamber of Commerce, argued that the added cost of state-mandated benefits is substantial,

[5] Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008. Public Law 110-343, 110th Cong., 2d sess. (October 3, 2008).

[6] Patient Protection and Affordable Care Act of 2010 as amended. Public Law 111-148 § 1331(d)(3)(B)(ii), 111th Cong., 2d sess.

referencing a study that indicated premiums rise by half a percent or more per mandated benefit, so as these mandates accumulate, costs aggregate (CAHI, 2010).

The California Health Benefits Review Program (CHBRP) is an example of independent public review of proposed state mandates before they become law. It reviews medical effectiveness, cost impact, and public health impact for each proposed mandate. Ms. Susan Philip pointed out that CHBRP researchers do not examine the full cost of adopting a mandate *de novo*. Rather, they examine the impact of adding a mandate, including changes in health care expenditures, premiums, and OOP costs compared to existing coverage levels already available in the market. In a recent analysis of the marginal cost of the state's 44 mandates compared with requirements already mandated for managed care by California's Knox-Keene Health Care Service Plan Act of 1975,[7] researchers determined there would be a 2 to 5 percent cost reduction in the absence of the current 44 mandates.

CONSIDERING SPECIFICITY AND FLEXIBILITY IN GUIDANCE

Many speakers, including patient advocates, employers, state policy makers, and insurers, emphasized the importance of allowing flexibility in benefit design. The "buckets of care" included in the ACA, Ms. Spangler said, were "intentionally left vague so that details of what plans would cover could be left to the marketplace." An argument against further specificity was supported by Representative James Dunnigan of the Utah State House of Representatives and Mr. Matthew Salo of the National Governors Association (NGA), both of whom urged the committee to allow state-by-state flexibility in implementation. Dr. Cowdry, for instance, cautioned the committee against "too much design specificity or standardization [in the EHB package]" as this prevents the kind of innovation needed to control health care costs.

On the other hand, other stakeholders expressed concerns about too much flexibility in benefit design. Ms. Cindy Ehnes, the Director of California's Department of Managed Health Care (DMHC) described the DMHC's experiences with health benefits provided under California's Knox-Keene Health Care Service Plan Act of 1975. While broad categories of benefits allow for flexibility as new diagnoses and treatments become recognized standards, broad categories create uncertainty about whether a treatment must be covered by a plan. This latter concern has resulted in numerous state-mandated benefits. Defined benefits, she said, eliminate this uncertainty by providing clarity about whether a particular service is covered, but may increase the risk that something not specifically defined will be considered excluded. On behalf of the American Congress of Obstetricians and Gynecologists (ACOG), Dr. Arnold Cohen said that describing the EHB as specifically as possible "is the surest way to protect our patients against potential conflict or debate regarding medical necessity."

DETERMINING MEDICAL NECESSITY

HHS asked the committee to explore how insurers determine medical necessity. Dr. Alan Garber, the director of the Center for Health Policy at Stanford University, explained the differences between the delineation of included and excluded services in a benefit package and the application of medical necessity. The scope of coverage in a health insurance contract is a policy decision based on the expected general needs of the insured population, whereas a medical necessity determination assesses whether the intervention is appropriate for a specific patient and thus eligible for payment by the insurer. He reviewed some precedents, including a definition developed by a committee convened by Stanford University, and a definition agreed to by several large insurers as part of a class action lawsuit settlement.

Additional medical necessity definitions were offered. For example, Dr. Cohen of ACOG asked the committee to consider adopting the definition of medical necessity developed by the AMA, and advised clarifying that physicians are practicing "in accordance with generally accepted standards" if they adhere to the guidelines developed and adopted by their respective medical specialty. Similarly, Dr. Andrew Racine of the American Academy of Pediatrics (AAP) noted that AAP's "Policy Statement on Contractual Language for Medical Necessity for Children" supports the use of evidence-based interventions, but because large scale randomized controlled trials are "signifi-

[7] California Knox-Keene Health Care Service Plan Act and Regulations of 1975. California Health and Safety Code Chapter 2.2 § 1340.

cantly less plentiful" for children than for adults, observational studies, professional standards of care, or consensus of pediatric expert opinion must serve as acceptable substitutes. Ms. Meg Booth of the Children's Dental Health Project endorsed the definition of dental necessity in The Children's Health Insurance Program Reauthorization Act of 2009[8] (CHIPRA) and the maintenance of parity in dental benefits for prevention, restoration, and treatment.

Patient advocates identified interpretation of medical necessity definitions as presenting a potential barrier to meeting the medical needs of specific types of patients. Additionally, Ms. Linda Fishman of the American Hospital Association (AHA) identified the lack of consistent standards as affecting both providers and patients as it "allows insurers to control not only coverage decisions but also treatment decisions, sometimes overriding clinical standards and the patient's needs." The rules and decision processes that govern EHB and medically necessity should, she said, be transparent so that enrollees understand in advance the limitations of their coverage. Mr. Troy Zimmerman from the National Kidney Foundation cautioned that "vague definition(s)" of what is medically necessary can inhibit innovation and patient choice. Mr. Peter Thomas of the Consortium for Citizens with Disabilities, and Ms. Marty Ford of the United Cerebral Palsy Disability Policy Coalition illustrated how definitions of medical necessity that focus only on restoring function without consideration of maintenance or acquisition of function have presented barriers to care for people with disabilities, especially developmental disabilities. Similarly, Dr. Gary Ulicny of the Shepherd Center said the primary goal of rehabilitation is to decrease the patient's reliance on medical intervention and to increase functional independence rather than necessarily providing a cure. Applications of definitions of medical necessity that require the intervention "to cure" present roadblocks to reimbursement for needed care. Mr. Paul Samuels of the Legal Action Center expressed that individuals with mental health and substance use disorders need to be able to access the type, level, amount, and duration of care that they need, including care for relapses. Thus, medical necessity criteria should reflect the chronicity of mental illness and substance abuse disorder.

Medical necessity reviews by insurers, Ms. Bocchino pointed out, are not conducted on most services that individuals receive every day. These reviews "come into play" if questions arise regarding a lack of evidence for such treatment, concerns about clinical effectiveness or potential harm, or if a patient did not meet the subpopulation characteristics for which the intervention might be prescribed.

PROMOTING VALUE IN INSURANCE BENEFIT DESIGN

Many employers, insurers, and some states as well are adopting value-based insurance design (VBID) to reduce excessive and inappropriate utilization and improve quality. Dr. Cowdry suggested comprehensive coverage may "be the right place to be" if such coverage can be merged with value-based incentives for patients and providers, and if there is a rigorous process to exclude non-medically necessary interventions. State exchanges, he suggested, "can be laboratories for exploring different limits and the kind of cost-sharing designs that make sense."

Participants who discussed VBID principally described two considerations: evidence and setting appropriate incentives. Dr. Nussbaum of WellPoint, Inc. explained this concept by describing a diabetes management program in which an employer plan waived all co-pays for diabetes medications, steered patients to higher quality hospitals and physicians, removed deductibles for preventive care (before the ACA mandated the removal of these deductibles), and provided free diabetes education and support. While the program increased short-term costs, it has the potential to demonstrate long-term savings from higher medication compliance and use of preventive services. Similarly, Mr. Brian Gallagher of the American Pharmacist Association advocated for mechanisms to optimize medication use through medication therapy management services, and he pointed out that medication use can be optimized by removing barriers such as co-pays and deductibles and by empowering patients to take an active role in medication self-management.

Dr. Somnath Saha, the chair of Oregon's Health Services Commission (HSC), and Dr. Jeanene Smith, the administrator of Oregon's Office for Health Policy and Research (OHPR), provided insights into Oregon's process for setting priorities for its Medicaid program and new efforts with value-based tiers of coverage for the private sector. The HSC maintains a prioritized list of covered services that are "rank-ordered" according to impact on

[8] The Children's Health Insurance Program Reauthorization Act of 2009. Public Law 111-3, 111th Cong., 1st sess. (February 4, 2009).

health, treatment effectiveness in improving and promoting health, and public values. The state legislature then uses this prioritized list to determine which benefits the state can afford to cover. The prioritized list is being used to design value-based tiers of coverage for the commercial market: the highest "value-based" tier includes tests and treatments that are highly effective, low cost, and that are considered desirable to encourage in the population. Thus, the highest value services would have the lowest cost sharing.

Utilization management, network design, and the exclusion of specific services (i.e., contractual exclusions, and the exclusion of services deemed experimental, investigational, or not medically necessary) were cited by presenters as components of benefit design that insurers employ; any package of defined benefits is subject to such rules, which can vary from plan to plan. Insurers and employers view these, along with medical necessity determination, as ways to better ensure appropriate care as well as manage costs. However, Ms. Jina Dhillon of the National Health Law Program (NHeLP) cautioned that insurers' steps for medical utilization management need special oversight. For instance, step therapy may be an effective strategy for providing safe, cost-effective care, but she suggested that there be an exceptions process that allows "first fail"[9] to be avoided if there is an important clinical reason for pursuing a different medical option in individual cases.

APPLYING EVIDENCE TO BENEFIT COVERAGE

Uniformly, speakers supported the use of evidence in deciding which benefits should be covered in an essential package, and in developing clinical policies by insurers and guidelines by provider groups that identify the care patients should be eligible to receive. Several speakers specifically endorsed comparative effectiveness research. It was pointed out, however, that different entities may come to different conclusions about whether to cover a specific benefit or not. These decisions may have to do, not only with the evidence base, but also with the cost of adding a benefit, the importance of including the benefit to the potential purchaser, and competition in the marketplace, among other considerations.

Washington State employs a transparent hierarchy of evidence in deciding which benefits it will cover. Dr. Jeffery Thompson, the chief medical officer of Washington State's Department of Social and Health Services and the Health Care Authority, described how a service supported by "A-level evidence based on randomized trials" is likely to be added to the state benefit package. For example, before the introduction of the evidence-based benefit design approach, cardiac rehabilitation was not a covered benefit. Once reviewed, however, A-level evidence showed cardiac rehabilitation helped to avoid further surgery, hospitalization, and subsequent heart attacks; the benefit is now paid for. Covered benefits are not limited to those that only have A- or B-level evidence; there is room for consideration of lower level evidence and experimental and investigational treatment. Furthermore, as new technology-related benefits can be beneficial for patients but costly for insurers and purchasers if used indiscriminately, Ms. Leah Hole-Curry described the complementary Washington State Health Technology Assessment (HTA) program. First, they consider efficacy and safety to determine the degree of variation between how the technology functions in the "best environments" and the "real world." Only after a technology has "passed" the tests of efficacy and safety do they consider "the cost question." Of the 20 evaluations HTA has undertaken, they have considered cost for only "a few," either because the technology has not gotten through the "first two hoops," or because the "first two hoops answer the question and cost becomes immaterial because there is value that's uniquely provided by the technology."

Private insurers similarly evaluate new technologies for coverage and review evidence for the development of clinical policies that are applied in medical necessity determinations. When Aetna evaluates a new technology for coverage, the insurer, Dr. Robert McDonough said, considers whether the technology has final approval from governmental regulatory bodies and the scientific evidence supporting the effect of the technology on health outcomes. Aetna was the first to publish its clinical policies on its website, and now other insurers are following this practice.

In the face of less evidence than is often needed to make evidence-based coverage decisions, "it is critically important," Dr. Calega said, that the nation devote funding to develop more evidence, including comparative effec-

[9] Under "first fail" policies, patients are first treated with the most cost-effective drug therapy. The patient progresses to more costly therapies only if clinically necessary.

tiveness research (CER). Ms. Philip said, for example, that in the absence of comparative effectiveness research, CHBRP was unable to compare the effectiveness of an injectable cancer medication with an oral cancer medication. Ms. Darling noted that comparative effectiveness research will "provide us with very valuable information about how to fine tune" coverage decisions. Similarly, Ms. Fishman said, limits placed on the EHB package could focus on services that are marginally effective and could change as underlying scientific evidence or CER informs clinical best practices.

Insurers may choose to exclude certain services from coverage altogether or limit access to certain clinical circumstances, but providers and consumers raised questions about timely access to what they deem evidence-based services. For example, cosmetic surgery and bariatric surgery are sometimes excluded from policies. Dr. Robert Murphy of the American Society of Plastic Surgeons (ASPS) maintained that there are an increasing number of insurers denying plastic surgery for children born with disfiguring birth defects by labeling the procedures "cosmetic" or "non-functional" in nature, requiring many time-delaying appeals. Similarly, Dr. Bruce Wolfe of the American Society for Metabolic and Bariatric Surgery said access to obesity prevention and treatment is severely limited despite a growing body of evidence supporting intervention.

Consumers and providers also argued for flexibility in application of standards of evidence to ensure patients have access to care. Mr. Thomas, for instance, noted that "you go with the highest level of evidence you have," but have to be careful about rigid application in all circumstances. Dr. Cohen concurred with the need for flexibility; the EHB package, he argued, must allow for medically appropriate off-label use of FDA-approved drugs and devices, a common practice in OB/GYN. Similarly, Mr. Thomas Sellers of the National Coalition for Cancer Survivorship (NCCS) remarked that Medicare's policy of covering clinical trials has "yielded significant benefits for individual patients and for the health care system" because patients are permitted to enroll in trials without fear that their routine costs will be denied and the enrollment of patients in the trial furthers evidence development (CMS, 2011).

MONITORING REQUIRED ELEMENTS FOR CONSIDERATION

Section 1302 specifies certain "required elements for consideration," the core of which are that the Secretary shall (1) ensure that the EHB "reflect an appropriate balance among the categories"; (2) not make coverage or benefit decisions that "discriminate against individuals because of their age, disability, or expected length of life"; (3) take into account the health care needs of diverse segments of the populations; and (4) ensure that EHB are not subject to denial against individuals' wishes on the basis of age, expected length of life, present or predicted disability, degree of medical dependency, or quality of life.

Regarding the consideration of "appropriate balance" among the categories of care, the committee heard perspectives from health care providers, industry, and consumers. Dr. Gerald Harmon, provided the AMA's position that rather than striving for an appropriate balance, "the goal should be to assure parity in terms of access and coverage" for each category. Mr. Falardeau shared the American Chiropractic Association's opinion that the top priority should be to ensure a complete essential benefits package, as opposed to having an equal number of services in each of the 10 categories. For example, there may be a relatively large number of ambulatory services that could be considered essential and fewer hospitalization services that could be considered essential. Mr. Richard Smith, speaking for the Pharmaceutical Research and Manufacturers of America, also cautioned HHS to consider "rapid changes in the patterns of care." He explained that when health insurance first originated, there were fewer effective pharmaceutical treatments available. The availability of treatments for acute and chronic conditions have changed significantly with time, yet insurance benefits often seem to reflect more traditional patterns of care.

Ms. Sara Rosenbaum from the George Washington School of Public Health and Health Services argued that the required elements for consideration provision is designed to address the issue of insurer discretion to discriminate against certain types of conditions in the context of benefit design and coverage determinations. In some cases, excluded conditions may be quite specific, while in others a proxy of "recovery" or "restore" is commonly used to differentiate chronic conditions for which there may be no "recovery" from those that are acute and time-limited and for which recovery is possible. Disability and age both raise this issue, since age can affect the potential for recovery and because individuals with developmental disabilities may never recover. The question should be whether treatment aids functioning and serves to maintain health or avert a deterioration in health, not whether

recovery can be expected. Ms. Rosenbaum further suggested that one way to minimize insurers' discretion would be to caution insurers about using medical necessity definitions that inherently discriminate by limiting coverage only to "medical conditions." Such a definition, she said, would discriminate against individuals with developmental disabilities as these are often not considered medical conditions. The central question is whether the treatment in question is medical in nature and whether the individual can be expected to medically benefit from the treatment. In her opinion, that the health benefit will have spillover effects in educational, employment, or social contexts should be irrelevant to the coverage determination.

From the health care provider perspective, Dr. Harmon said that age, disability, and gender, among other considerations, have to be taken into account by the "prudent physician" in deciding clinical care. Ms. Rosenbaum agreed that the use of patient characteristics such as age that rest on a reasonable clinical and scientific evidentiary base are not discriminatory (e.g., immunizing a child at a specific age).

Dr. Harmon also argued that strong physician-patient relationships allow physicians and patients to jointly participate in making value-based health care decisions to determine the patient's wishes. As an example, Dr. R. Sean Morrison, Director of the National Palliative Care Research Center, advocated for the inclusion of palliative care in the EHB package, noting that under the current insurance model the only reimbursement for palliative care is via hospice, which some insurance companies do not even cover. He cited a study showing how palliative care can reduce hospital costs as well as better meet patient and family goals to spend less time or die in intensive care. Having the benefit available would allow physicians to provide options in accord with the patient's wishes.

INSTITUTING AN APPEALS PROCESS

ACA requires health insurance plans to have internal and external grievance and appeals processes; therefore, appeals processes were discussed by several presenters. Health plans, Ms. Bocchino said, "fully support a fair, robust, and timely process for consumers to appeal benefit denials through external review administered by independent third-party review organizations." Dr. Kang noted that CIGNA Corporation's internal appeals process serves an important function, but is infrequently needed: last year, approximately 99 percent of its U.S. claims were paid without any denial or required pre-authorization. After the appeals process was exhausted, about .006 percent of the total number of claims were ultimately denied.

California's Knox-Keene Act provides one model of an existing independent external appeals process, such as ACA requires to be developed in each state. Knox-Keene mandates plans operating in California to have an internal process for resolving enrollee grievances, and when enrollees have exhausted this process, they can appeal to the state. A team from the California Department of Managed Health Care, described the main classifications of appeals (i.e., medical necessity determinations, experimental and investigational therapies, and emergency room use), treatments and conditions experiencing the most frequent reviews, and how often appeals were upheld or overturned. Ms. Ehnes said one of her principal concerns as director is that patients have to raise the complaint so there must be a process where people "who do not complain are able to start accessing the advances in science and medicine." Accordingly, each appeal provides the insurance regulator an opportunity to consider if there is a more widespread problem.

ENSURING FAIR PROCESSES

Another theme raised by several presenters was the challenge of making information transparent to consumers, whether it be clinical policies, medical necessity decisions, or scope of coverage in a plan. On behalf of Consumers United for Evidence-Based Healthcare (CUE), Dr. Barbara Warren advocated for the inclusion of educated consumers in making benefit design decisions and in defining medical necessity. Consumer participation, she argued, pays off in that consumers can provide insights and perspectives that are often not apparent to clinicians, policy makers, and industry representatives. Consumers, Dr. Warren acknowledged, are often misrepresented as being opposed to limits or not willing to discuss what care might be essential and necessary.

As the committee considers methods to determine and update EHB, some speakers thought the processes used by states to transparently evaluate benefits—whether through reviews of state mandate proposals, appeals of denials

of care, or benefit design processes—might provide important insights for methods to define EHB. California and Oregon, for instance, have established processes for gaining stakeholder buy-in. For example, Ms. Philip of the CHBRP made a case for independence and transparency as California has in the state mandate evaluation process. The transparency of CHBRP's processes, she added, has helped improve its methods while enhancing the credibility and reliability of its reports. Mr. Wright of Health Access California supports independent medical review processes of insurance company denials, he said, because they address the key consumer concern: transparency. Likewise, Mr. Thomas from the Consortium of Citizens with Disabilities advocated for transparent processes, including the formation of a formal advisory body to update the EHB package.

ORGANIZATION OF WORKSHOP REPORT

This report is organized to reflect the two workshops, with the January workshop comprising Chapters 2-9 and the remainder, the March workshop.

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1

Introduction[1]

The Patient Protection and Affordable Care Act (herein known as the Affordable Care Act [ACA]) was signed into law on March 23, 2010. Several provisions of the law went into effect in 2010 (including requirements to cover children up to age 26[2] and to prohibit insurance companies from denying coverage based on preexisting conditions for children[3]). Other provisions will go into effect during 2014, including the requirement for all individuals to purchase health insurance.[4] Purchasers are allowed, but not obliged, to buy their coverage through newly established health insurance exchanges (HIEs)—marketplaces designed to make it easier for customers to comparison shop among plans and for low and moderate income individuals to obtain public subsidies to purchase private health insurance.

EXCHANGES AND ESSENTIAL HEALTH BENEFITS

The exchanges will offer a choice of private health plans, and all plans must include a standard core set of covered benefits, called essential health benefits (EHB). The health insurance exchanges will only offer qualified health plans (QHPs), meaning the plans are deemed to cover the EHB and to meet other requirements set by the ACA. In the initial years, the exchanges are open to individual purchasers and employees of small businesses (i.e., with 100 or fewer employees);[5] starting in 2017, a state can decide whether to open its exchanges to larger employers. Additionally, the EHB are required to be included in new private individual and small group health

[1] The report summarizes the views expressed by workshop participants, and while the committee is responsible for the overall quality and accuracy of the report as a record of what transpired at the workshop, the views contained within the report are not necessarily those of the committee. Of note, figures, sources, and citations were provided by presenters in support of their testimony, and are not necessarily endorsed by the committee.

[2] Patient Protection and Affordable Care Act of 2010 as amended. Public Law 111-148 § 1001, adding § 2714 to the Public Health Service Act, 111th Cong., 2d sess., as revised by § 2301(b) of the Health Care and Education Reconciliation Act of 2010.

[3] § 1101.

[4] Exemptions will be granted for financial hardship, religious objections, American Indians, those without coverage for less than three months, undocumented immigrants, incarcerated individuals, those for whom the lowest cost plan option exceeds 8 percent of an individual's income, and those with incomes below the tax filing threshold (in 2009 the threshold for taxpayers under age 65 was $9,350 for singles and $18,700 for couples) (§ 1501 and § 10106; adding Internal Revenue Code § 5000A(c)).

[5] ACA states that a small firm or employer is defined as one with 100 or fewer employees (§ 1304(b)(2)); however, until 2016, states may opt to define small firms as those with 50 or fewer employees (§ 1304(b)(3)).

BOX 1-1
Essential Health Benefits Categories in ACA

Essential Health Benefits

- Ambulatory patient services
- Emergency services
- Hospitalization
- Maternity and newborn care
- Mental health and substance use disorder 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

SOURCE: § 1302(b)(1)(A)-(J).

insurance plans offered outside of the exchanges. Publicly supported subsidies, however, will only be available to those purchasing private plans through the exchanges, and these subsidies will be computed on a sliding schedule for individuals whose incomes are between 133 and 400 percent of the federal poverty level.[6] Certain public insurance programs (i.e., Medicaid benchmark/benchmark-equivalent plans; state basic insurance) also must include the EHB package.[7]

Section 1302 of the ACA stipulates that the Secretary of the U.S. Department of Health and Human Services (HHS) is to define the EHB (Appendix A). The EHB must include "at least" 10 general categories of care and be "equal in scope to those offered by a typical employer plan."[8] The 10 broad categories are outlined in Box 1-1.

STUDY CHARGE AND APPROACH

At the request of the Secretary of HHS, the Assistant Secretary for Planning and Evaluation (ASPE) contracted with the IOM to make recommendations on criteria and methods for determining and updating the EHB package. It is important to note that the IOM Committee on Defining and Revising an Essential Health Benefits Package for Qualified Health Plans was not formed to detail the specific service elements of the benefits package, but rather, the committee was asked to offer advice on policy foundations, criteria, and methods for defining and periodically updating the benefits package. The specific statement of task for this committee is presented in Box 1-2.

To hear a variety of viewpoints on issues contained within the committee's charge, the committee held public workshops on January 13-14, 2011, in Washington, DC, and March 2, 2011, in Costa Mesa, California. Experts from federal and state government, employers, insurers, providers, consumers, and health care researchers were asked to identify current methods for determining medical necessity, express state-specific concerns, and share decision-making approaches to determining which benefits would be covered and other benefit design practices,

[6] Individuals whose incomes are at or below 133 percent of the federal poverty level (FPL) will be eligible for Medicaid (a 5 percent income disregard effectively raises the eligibility level to 138 percent of FPL). The EHB do not apply to the traditional Medicaid program, although they are applicable to state expansions of insurance for low-income individuals, called Medicaid benchmark or benchmark-equivalent plans (§ 2001(c)), and state basic health insurance (§ 1331).

[7] Exchanges may also be a vehicle for determining eligibility for traditional Medicaid and other state programs, even though those do not require inclusion of the EHB, and for matching individuals to the appropriate public or private options.

[8] The Department of Labor was required by law to conduct a survey on the typical employer plan. Survey results can be found at: http://www.bls.gov/ncs/ebs/sp/selmedbensreport.pdf (accessed April 19, 2011).

BOX 1-2
Statement of Task for the IOM Committee

The Patient Protection and Affordable Care Act (Affordable Care Act) established criteria for qualified health plans (QHPs) to participate in exchanges as defined in Section 1301 of the statute. An ad hoc IOM committee will make recommendations on the methods for determining and updating essential health benefits for QHPs based on examination of the subject matter below.

In so doing, the committee will identify the criteria and policy foundations for determination of the essential health benefits offered by QHPs taking into account benefits as described in Sections 1302(b)(1) and 1302(b)(2)(A), and the committee will assess the methods used by insurers currently to determine medical necessity and will provide guidance on the "required elements for consideration" taking into account those outlined in Section 1302(b)(4)(A-G), including ensuring appropriate balance among the categories of care covered by the essential health benefits, accounting for the health care needs of diverse segments of the population, and preventing discrimination against age, disability, or expected length of life. The committee will also take into account language in Section 1302 on periodic review of essential health benefits, and other sections of the Affordable Care Act: for example, coverage of preventive health services (Section 2713), utilization of uniform explanation of coverage documents and standardized definitions (Section 2715), and other relevant tasks found in the Affordable Care Act for the Secretary of HHS. The committee will provide an opportunity for public comment on the tasks of defining and revising the essential health benefits.

among other topics. A month prior to the first workshop, the committee posted a set of questions online for public comment (Appendix B); these questions were posted for six months and the comments informed the committee study process.

The following chapters describe and summarize workshop presentations and discussions between the presenters and the committee; ASPE requested, as part of the committee's work, the publication of a report of the workshop proceedings. This document does not summarize the responses to the public comment form, which were provided to ASPE in their entirety. The views expressed are those of the workshop participants, not necessarily those of the committee. While committee members often ask probing questions, those questions should not be interpreted as positions indicative of personal or committee views. At the time of the workshops, the committee had not reached any conclusions; similarly, this workshop report does not present committee conclusions. Rather, this document is a factual summary of the two workshops, focusing in turn on each panel discussion. Every presenter was afforded the opportunity to review their individual portion of the following chapters prior to publication.

The committee acknowledges that this workshop report includes a variety of viewpoints about which different conclusions and therefore ramifications may result; however, these differences will not be reconciled in this report. Instead, the committee will use this information along with other sources when drafting its separate consensus report to provide guidance to the Secretary on defining and revising the essential health benefits. Furthermore, the content of this workshop report is limited to the views presented and discussed during the workshops and is not intended to be a comprehensive assessment of all issues pertaining to this subject. Readers should be aware that there may not always be countervailing opinions pressed on each issue.

2

The Policy Context for Essential Health Benefits

The complexities of implementing Section 1302 of the Patient Protection and Affordable Care Act (ACA) were apparent in presentations and discussion reflecting the perspective of the U.S. Department of Health and Human Services (HHS) on the Institute of Medicine (IOM) committee's task and Congress' intent for the EHB package. Dr. Sherry Glied, Assistant Secretary for Planning and Evaluation (ASPE) and study sponsor, reviewed HHS's objectives for the commissioned study and highlighted several questions on which HHS is seeking guidance. Next, a bipartisan panel of former and current Congressional staff members provided contrasting insights into Congress' intent in legislating Section 1302. Third, given the ACA's requirement that the Secretary of Labor conduct a survey of employer-sponsored coverage to inform HHS about the benefits "typically covered by employers," Department of Labor (DOL) representatives explained the DOL's survey methodology and approach to gathering information from employers.

PRESENTATION BY DR. SHERRY GLIED, ASSISTANT SECRETARY FOR PLANNING AND EVALUATION (ASPE), HHS

The discussion of the essential health benefits (EHB) in Section 1302 amounts to only a handful of pages of the ACA, but these few pages, Dr. Glied said, "will influence the nature of coverage available to millions of people in the United States." Dr. Glied began by reviewing the purpose of the IOM study, describing ASPE's expectations, and clarifying that ASPE does not "expect the committee to identify the individual elements or the detailed provisions of a package of essential health benefits." Instead, ASPE is asking the committee to develop a framework for considering the EHB. Such a framework would be "logically cohesive, address statutory requirements, and serve HHS now and in the future."

Dr. Glied reiterated that beginning in 2014, the EHB are required to be offered by qualified health plans participating in health insurance exchanges,[1] insurance plans in the individual and small group markets outside the exchange,[2] Medicaid benchmark and benchmark equivalent plans,[3] and state basic health programs for low-income individuals not eligible for Medicaid.[4] In response to an inquiry from committee member Dr. John Santa, Dr. Glied

[1] Patient Protection and Affordable Care Act of 2010 as amended. Public Law 111-148 § 1301(a)(1)(B), 111th Cong., 2d sess.
[2] § 1201, amending Public Health Service Act by inserting § 2707(a).
[3] § 2001(c).
[4] § 1331(b)(2).

said these Medicaid benchmark plans are a "distinct entity" from current Medicaid programs. Benchmark plans may have a scope of coverage different from the usual mandatory Medicaid coverage.

Further, Dr. Glied noted, the ACA explicitly permits continuation of utilization management practices in common use at the time of enactment by group health plans and health insurance issuers, and bars the issuance of regulations that would prohibit their use.[5] In response to further inquiry from Dr. Santa, Dr. Glied clarified that ASPE does not expect the IOM committee to identify these commonly used utilization management practices, but said that when the Chief Actuary of the Centers for Medicare & Medicaid Services determines the EHB package is equal in scope to that of a typical employer and determines actuarial value, the actuary "will look at what is actually in practice in the world and make estimates on that basis."

Dr. Glied drew attention to several elements of Section 1302, including those pertaining to the need for the EHB to be balanced among categories, be non-discriminatory, and include a scope of benefits equal to the scope of benefits provided under a typical employer plan. In addition, she said the committee could provide ASPE with guidance on the following types of questions:

- At what level of specificity should EHB be framed?
- What can be learned about plan design, consistency, and fairness from the practices of employers who offer multiple plans?
- Assuming that insurers continue to have a role in deciding which services to pay for, what information is needed to monitor the decisions that are made, how should that information be collected, and how should that information be used, if at all, in updating the EHB? What are the roles of exchanges, states, and the federal government in this task?
- How are issues of time, duration, frequency, scope, and specific services best addressed?
- What defines and distinguishes a medical service from a nonmedical service? How should this distinction be considered and applied in the context of defining EHB?
- How can a federal standard for benefit coverage best reconcile existing state and regional variations in practices and benefit coverage patterns, including variations in state-mandated benefits?
- How much flexibility should be given to states and/or the exchanges?
- What criteria should be used to adjust EHB over time and what should the process be for their modification? How can modifications to EHB remain consistent with the initial benefit design while reflecting evolving science?

Committee member Dr. Alan Nelson asked Dr. Glied to further elaborate on ASPE's request that the committee "define and distinguish a medical service from a nonmedical service." The EHB package, Dr. Glied responded, is intended to cover "those medical services that are required under essential health benefits." One of the considerations that will logically arise, then, is what actually defines a medical service. While there are "many, many things that contribute to a person's health," not all of them are medical services. ASPE envisions the EHB package as including only those components deemed to be "medical," and that would fall within a typical insurance package.

Given the legislative requirement that EHB are equal in scope to the benefits under a typical employer plan, committee chair Dr. John Ball asked Dr. Glied to speak about the potential contradiction between benefits that may be essential vs. those that may be typical. Dr. Glied noted that this contradiction may be particularly apparent around the issue of nondiscrimination. "Thinking through how we develop an essential health benefits plan that meets both the requirements of the law that says 'typical employer' and says 'nondiscriminatory' is something we would like your advice about," she said. Committee member Ms. Marjorie Ginsburg noted that other contradictions may arise if "typical" plans include benefits that are not "essential." Dr. Glied confirmed the truth in this observation, but suggested the committee "focus more on the process than on the content of the plan." This exchange prompted committee member Dr. Elizabeth McGlynn to ask for more details on what is "typical," asking, "Should typical reflect the markets that these plans will be issued in" or should it be the "average" typical plan? Because

[5] § 1563(d)(1).

the legislation, Dr. Glied noted, "is silent on what is meant exactly by typical," the committee's interpretation of this term would be useful to ASPE.

ASPE recognizes the need to provide clear direction to the states and insurance industry, understands that the ACA obligates states to pay for benefits they mandate beyond those required by the Secretary, acknowledges the need for flexibility across states, and appreciates the need to provide meaningful coverage while assuring an affordable premium. Above all, she said, HHS "strives to remember the interests of consumers and patients." When committee member Mr. Leonard Schaeffer asked for guidance as to whether "affordable implies both affordable for the individual and affordable for the government," Dr. Glied suggested that the IOM committee remain mindful of the cost of coverage as it considers the EHB. In response to an inquiry by committee member Mr. Christopher Koller, she confirmed that the committee's task "is not about the actuarial value of the benefit. It is about what the scope of the benefit is in terms of the essential health benefits." Dr. Glied concluded by informing the committee and audience that the IOM and ASPE were currently reviewing over 300 responses to a web-based IOM public comment form (Appendix B).

LEGISLATIVE INTENT

Mr. Mark Hayes, Ms. Katy Spangler, Mr. David Schwartz, and Dr. David Bowen, all of whom were working for elected officials involved in the evolution of the EHB provision in the ACA, agreed that the legislature intended for the EHB to be a set of benefits constrained by the scope of benefits offered by a typical employer yet reflected at least the 10 categories of care in Section 1302. Disagreement emerged about what employer size should be considered typical and thus the degree of comprehensiveness in the benefit package, but presenters noted the language of Section 1302 was subject to relatively "little debate" in the House or Senate. The presenters agreed that in terms of the degree of specificity on benefits within the bill, the legislative language was more general and was not to reflect the more detailed benefit descriptions that were included in President William Clinton's Health Security Act.[6] Greater detail was expected during implementation at the federal, state, and health plan levels.

THE REPUBLICAN PERSPECTIVE

The committee first heard testimony from two congressional staff members present during Republican health reform discussions. Mr. Mark Hayes spoke from his experience as the Health Policy Director and Chief Health Counsel for the Senate Finance Committee working under Committee Ranking Member Charles Grassley (R-IA), while Ms. Katy Spangler drew from her experience as a Senior Health Policy Advisor for the Senate Health, Education, Labor, & Pensions (HELP) Committee as well as through her work for Senator Mike Enzi (R-WY).

PRESENTATION BY MR. MARK HAYES, GREENBERG TAURIG, LLP

Mr. Hayes began by speaking of the origin of Section 1302, explaining that "the basic framework of the benefit structure" originated in the Senate Finance Committee and remained "structurally intact" throughout the various iterations of the bill and ultimately in the law. The ACA uses the term essential, he pointed out, because the legislature intended these to be basic not comprehensive benefits. The legislation did not intend for a Medicare- or Medicaid-like prescriptive benefit design. Instead, the Secretary of HHS was intended to define and update the categories of covered treatments, which, in turn, generally results in coverage for the items and services within broad benefit classes, but with "detailed benefit designs defined in the private market."

The Senate Finance Committee, he said, evaluated numerous models when it framed the EHB package. It ultimately rejected fee-for-service (FFS) Medicare because its benefit package is "defined at the federal level in great specificity" and has remained "largely unchanged" since 1965. While Medicare Part C (Medicare Advantage plans) has "additional flexibility for benefit design," the plans must still cover all of the benefits of traditional fee-for-service Medicare. Medicare supplemental plans are also "very prescriptive and detailed," as were the benefits

[6] Health Security Act of 1993, HR 3600, 103rd Cong., 1st sess., Congressional Record (November 20, 1993).

specified in the Health Security Act.[6] Instead, the Finance Committee focused on the Federal Employees Health Benefits Program (FEHBP) and the Massachusetts Health Care Reform Law[7] as both programs "define very broad categories of benefits" and rely on an actuarial equivalence standard.

As further evidence of the legislature's intent, Mr. Hayes noted that if Congress intended to have a prescriptive benefit package as detailed as the 61 pages of benefits explicated in the Health Security Act,[6] it would be likely that the 60 percent actuarial package (i.e., the ACA's bronze plan) would need to have very high cost sharing, which would be "self defeating for the structure of the design." When committee member Dr. David Guzick asked for more details about determining this actuarial value, Mr. Hayes replied that the actuarial analysis would be governed by accepted standards for actuarial equivalency and will likely be overseen at both the state and federal levels when these packages are implemented. In response to a query by Mr. Koller on guidance from HHS to states, Mr. Hayes noted that the exchanges themselves are "tasked to find affordable choices of health benefit plans" and to grade these plans based on criteria developed by the Secretary of HHS. The ACA, he said, "empowers the exchanges to accept some very specific duties that I think point clearly to what the congressional intent was about how minimally specific the benefit design should be defined at the federal level."

Dr. Guzick noted that the categories in Section 1302 are defined in terms of types of services, but that "another way to think about health benefits is in terms of condition." How are benefits for particular conditions, he asked, accounted for in the list of benefits? The intent, Mr. Hayes reiterated, "was not to have Congress or the Secretary get to the level of specificity" needed to list condition-specific benefits. These condition-specific decisions "would be made in the marketplace to reflect evolving clinical knowledge, appropriate practices, and appropriate oversight at the state level by insurance commissioners."

In response to an inquiry from committee member Ms. Amy Monahan, Mr. Hayes noted that the Senate Finance Committee considered the role of state mandates, but wanted to avoid the politically difficult task of determining which benefits mandated at the state level should or should not survive at the federal level. Citing state-specific mandates for Lyme disease in Connecticut,[8] panelist Mr. David Schwartz supported the notion that state-mandated benefits often "make a lot of sense for certain states and really not as much sense for other states." The Committee, Mr. Hayes said, avoided the issue by including broad categories rather than specific benefits while specifying that state mandates beyond the federally determined EHB are acceptable and permissible, but that states need to "pay the difference for the additional subsidies required to pay for those additional benefits."

PRESENTATION BY MS. KATY SPANGLER, STAFF, SENATE HEALTH, EDUCATION, LABOR, & PENSIONS (HELP) COMMITTEE

Ms. Spangler began by expressing the importance of Section 1302 to members of the HELP Committee and by clarifying that while it is true that the section remained largely unchanged throughout the legislative process, it was "highly debated in both committee markups as well as on the floor" and that it was the "subject of many amendments during all of those processes." She then expressed the HELP Committee's "extreme concern about increasing premiums." This concern, she said, is shared by the President, the Democratic Senate majority, and the Republican minority. Throughout the health reform debate, she noted, the Obama administration "repeatedly said" that the ACA could decrease premiums for families by $2,500 a year (The White House, 2009). Furthermore, Ms. Spangler noted, if the EHB package is "so comprehensive" that small employers and uninsured individuals cannot afford it, the EHB package will run counter to the very premise of the ACA.

Notably, the bronze plan's actuarial value was actually lowered once the bill was reported out of the Finance Committee (from 65 percent to 60 percent), which demonstrates how important it is that Americans have access to plans with lower premiums. Further, after the bill was reported out of the Senate Finance committee, the eligibility criteria for catastrophic plans were expanded to give more Americans access to lower cost catastrophic plans. "We have seen in Massachusetts and with Medicare Part D," Ms. Spangler said, "that an overwhelming number

[7] An Act Providing Access to Affordable, Quality, Accountable Health Care. Chapter 58 of the Acts of 2006 of the Massachusetts General Court (April 12, 2006).

[8] Connecticut General Statute, Chapter 700c § 38a-492h.

of enrollees choose the lower cost plans even if that means the benefit packages are not as rich" (HHS, 2007; MA Health Connector, 2011). Choice, she reiterated, is important for Americans. In response to Ms. Spangler's comment, Ms. Ginsburg asked whether exchanges should be required to offer at least one plan that is "just the floor" to ensure an affordable plan is always available. The marketplace, Ms. Spangler responded, "will continue to demand those types of plans," and commissioners in the states "should ensure" that these affordable plans are available.

Echoing a point made by Mr. Hayes, the "buckets of care" included in the ACA, she said, were "intentionally left vague so that details of what plans would cover could be left to the marketplace." She also confirmed that while Congress looked to the FEHBP statute "as a model," the FEHBP benefits required in its authorizing statute are much less comprehensive than those that were included in the ACA. She cautioned the IOM committee against recommending that the EHB plan be "too" comprehensive: "the more regulations are published and more requirements are enacted, premiums will continue to increase, which will likely lead small employers to drop coverage."

"A lot rides on" the definition of EHB, Ms. Spangler warned. "In the post-2014 world," all new plans sold in the individual and small group markets must provide the EHB, and employers wanting to avoid a tax will have to provide qualified plans to employees. "It is critical," she advised, "that HHS not overreach in defining essential health benefits. Doing so would increase premiums and decrease choices to such an extent that fewer people will be able to afford health insurance."

She concluded by reiterating the importance of an affordable benefit package: if the benefit package is too comprehensive and thus too costly, more people will receive exemptions from the individual mandate, due to the premium exceeding a set percentage of their income. Mr. Hayes concurred, noting the penalties for not complying with the individual mandate are relatively light compared to expected premiums.

THE DEMOCRATIC PERSPECTIVE

Following presentations by Mr. Hayes and Ms. Spangler, the IOM committee gained additional insight into the congressional intent behind Section 1302 from those present during Democratic discussions, hearing testimony by Mr. David Schwartz, Acting Chief Health Counsel for the Senate Finance Committee and Dr. David Bowen, former Staff Director for Health Policy for the Senate HELP Committee.

PRESENTATION BY MR. DAVID SCHWARTZ, STAFF, SENATE FINANCE COMMITTEE

Mr. Schwartz expanded on the points raised by Ms. Spangler, including that the Senate Finance Committee aimed to ensure Congress did not "overreach." In 1993, for instance, the Health Security Act included "very specific, very detailed" provisions for the benefit package. Conversely, he said, in "crafting" the ACA, "Congress showed what its proper role is": to define large categories of care, and then allow the executive branch to "do its job implementing the law and dealing with the specific details." Congress intended, he said, "meaningful benefits so that when people get insurance, it will mean that they would really have access to health care."

To ensure the scope of the benefits would be "big enough so that people who get insurance through the exchange" have a meaningful package, the Senate Finance Committee "decided to link" the EHB standard to what is offered in typical employer plans. "It seems like a very reasonable concept," Mr. Schwartz said, "that there are millions and millions of Americans getting ESI [employer-sponsored insurance] and so let's use that as sort of a guardrail." Such a guardrail also helped ensure the EHB were both affordable and flexible. A second principle is that benefit packages have to allow for innovation, including advances in technology and treatments. The "approach" put in place in the ACA, he said, allows for the Secretary of HHS to design EHB that are both affordable and flexible.

When Mr. Schaeffer asked Mr. Schwartz to describe the legislative intent behind affordable (i.e., "Does it mean affordable to the individual who is covered or affordable to the government?"), Mr. Schwartz replied: "Our intent was to make it affordable from the perspective of an individual." Mr. Hayes added that members debated whether they meant affordability from the standpoint of the federal government and taxpayers, from the standpoint of low-income individuals, or from the standpoint of an average person. All of those standpoints, Mr. Hayes said, "are built into that one word."

PRESENTATION BY DR. DAVID BOWEN, THE BILL & MELINDA GATES FOUNDATION

Dr. Bowen echoed the comments of the previous speakers, saying that the language in Section 1302 is deliberately "very pared down" in terms of describing the benefit package. The HELP Committee, he said, made an early decision that "less is more" when describing EHB in the bill. In winter 2009, the HELP Committee staff convened a group of stakeholders from the Chamber of Commerce, Families USA, the American Medical Association (AMA), and labor unions to "talk about what the benefits package should look like" using four models: the few lines of text in the Massachusetts Health Care Reform Law,[9] two amendments promulgated by the Commonwealth of Massachusetts to flesh out the essential benefits defined in that law,[10] and the many pages in the Clinton reform bill.[11] These models provided two extremes: the Massachusetts law, he said, is "very, very brief" whereas the Clinton bill involved an enormous amount of detail. The committee intended, he said, for the EHB package description to be "somewhere in the middle."

After these discussions with stakeholders, Dr. Bowen "went away and wrote up something that was midway between" Massachusetts' first and second set of regulations; this text, he said, was "added to and modified a bit." However, he agreed with the earlier panelists that the text has "survived largely intact," though it includes several "important additions," including habilitative services.

Although the legislation does not say whether the "typical employer plan" should be for a small or large employer, "the general understanding that members [of Congress] had was this was a relatively generous package" that is "more typical of a relatively generous" large employer plan that contains "at least" the 10 categories of care. Similarly, Mr. Schwartz said the congressional committees identified "categories of care that we thought would lead to a robust benefit package and that would provide meaningful access to all kinds of care."

When committee member Dr. Joe Selby asked if the HELP Committee had considered how to more discretely specify the EHB or how to define medical necessity, Dr. Bowen noted that the HELP Committee purposely chose not to "sub-define" too many issues, as it would have "bogged" down the legislative process. He further stated that the HELP Committee did not make a distinction between medical and nonmedical services.

CONTRASTING VIEWS

Committee member Dr. Sam Ho pointed out the potential dichotomy between what Dr. Bowen and Mr. Schwartz described as a *robust benefit package*, and what Mr. Hayes and Ms. Spangler described as a *minimum benefit package* that was not intended to be comprehensive. Mr. Schwartz confirmed that the EHB package is intended to be meaningful, offering a "floor not a ceiling," while Ms. Spangler disagreed, noting that "I would just urge you again to look at the least robust version of the benefit package as meeting" the standard of minimum essential coverage.

When Mr. Schaeffer called attention to Mr. Hayes and Ms. Spangler indicating that "typical" meant a "small group, low cost" plan, Dr. Bowen said that he disagreed: the Senate did not intend for a the EHB package to be a "skimpy plan." While the EHB package is a minimum standard, Dr. Bowen reiterated that Congress intended this minimum to be consistent with a relatively generous large employer plan. Dr. Santa noted that the list of categories included in the ACA includes oral care, which is not included in "typical employer benefit plans." Mr. Hayes agreed that pediatric oral care is not generally covered under the FEHBP; this benefit, he said, was added during the amendment process.

DEPARTMENT OF LABOR (DOL) SURVEYS ON EMPLOYER-SPONSORED INSURANCE

Section 1302 requires the Secretary of Labor to conduct a survey of employer-sponsored coverage to determine the benefits typically covered by employers. Two representatives from the DOL, Joseph Piacentini, Office Director and Chief Economist, Office of Policy and Research, the Employee Benefits Security Administration (EBSA)

[9] An Act Providing Access to Affordable, Quality, Accountable Health Care. Chapter 58 of the Acts of 2006 of the Massachusetts General Court (April 12, 2006).

[10] 956 CMR: Commonwealth Health Insurance Connector Authority (July 1, 2007).

[11] Health Security Act of 1993, HR 3600, 103rd Cong., 1st sess., Congressional Record (November 20, 1993).

and William Wiatrowski, Associate Commissioner for Compensation and Working Conditions, Bureau of Labor Statistics (BLS), provided the IOM committee with background and a progress update on the survey, the results of which were later made available in April 2011.[12]

PRESENTATION BY DR. JOSEPH PIACENTINI, EBSA, AND MR. WILLIAM WIATROWSKI, BLS

Dr. Piacentini began by describing the role of the EBSA in administering employee benefits laws. In his role overseeing the agency's economic research, aspects of the ACA that address research projects, studies, and surveys related to job-based health benefits are under his aegis. While acknowledging that the survey of employer-based benefits "is a major undertaking," the DOL, he said, is utilizing its "very deep and rich data capabilities."

Mr. Wiatrowski then described the agency for which he works—the BLS—as the statistical arm of the DOL. The BLS provides nonpartisan economic data, and limits its role to providing data and analysis. The BLS, Mr. Wiatrowski reiterated, refers all policy issues to EBSA.

Survey Methodology

In conjunction with colleagues at HHS and EBSA, BLS identified the existing components of the National Compensation Survey (NCS) as appropriate to meet the ACA requirements for determining the benefits typically covered by employer-sponsored plans. For the past 30 years, the NCS has sampled small, medium, and large employers from the private sector, as well as state and local governments to collect data on benefit cost, incidence, and provisions. The data on government workers has been more limited than that collected for the private sector, but BLS is expanding that area.[13] Like other surveys conducted by BLS, the survey is voluntary and some employers, Mr. Wiatrowski said, choose not to participate. The NCS has a response rate of approximately 75 percent and uses standard statistical techniques to adjust for nonresponse.

Professional field economists employed by BLS contact each selected establishment to sample occupations, capture data on wages and benefits, and obtain copies of plan documents for health and retirement benefits. BLS then analyzes this information to obtain detailed provisions related to health and retirement benefits. Box 2-1 provides additional details.

Respondents to the survey are asked to provide cost and participation data for each offered benefit plan and the actual plan documents. Mr. Wiatrowski said the latter are used to identify whether their plan participants are subject to limits and, if so, for details on these limits (e.g., specific services, deductible, and co-insurance). Data are captured for all types of plans, including Employee Retirement Income Security Act (ERISA) plans and self-insured plans. While the multi-employer plans specifically mentioned in the ACA are captured by the survey, they are not identified separately in data outputs. Multi-employer plans, Dr. Piacentini said in response to a question from Mr. Schaeffer, are plans that are jointly sponsored by two or more employers and a labor organization. The benefits and the employer contributions are generally subject to collective bargaining and determined in advance. These large plans often include "very small" employers.

Health benefit plan documents range from formal, legal plan descriptions to brief comparison charts that describe multiple plans on a single page. BLS uses these documents to extract information on covered health care services and limits imposed by the plan. These results are presented as a percent of workers who participate in health care plans that cover these services and impose these limits. Dr. Ho asked if NCS's sample size allows for analysis by employer size, including employers with fewer than 50 employees. The data, Wiatrowski answered, are presented by employer size categories.

In summer 2010, HHS asked BLS for data related to the categories of services identified as essential in the ACA. BLS has used the plan documents from its most recent survey to develop information on 12 additional services and the limits imposed on those services (these data will not be sorted by size of employer).

[12] The report can be accessed on the BLS website: http://www.bls.gov/ncs/ebs/sp/selmedbensreport.pdf (accessed April 19, 2011). The testimony does not reflect the findings of the April report.

[13] BLS later released, covered services and limits in health benefit plans for state and local government workers, March 2011 available at: http://www.bls.gov/ncs/ebs/sp/smb_slgov.pdf (accessed April 19, 2011).

BOX 2-1
Characteristics of the National Compensation Survey

- **Sample size:**
  Total: ~36,000 establishments—Current Data Run: ~3,200 establishments
- **Provides data on:**
  - employer costs for wages and benefits
  - occupational wages by location
  - benefit availability
  - detailed benefit provisions of health and retirement benefits
- **In the case of health care benefits, respondents are asked to:**
  - identify each plan offered to each of the occupations
  - provide cost and participation data by plan
  - provide a copy of the plan description
- **Unit of observation:** occupation
- **Data subsets**
  - **worker characteristics** (occupational group, union status, full-time/part-time status)
  - **establishment characteristics** (industry, employment size, regional location)

SOURCE: Wiatrowski, 2011.

Survey Capabilities

At the time of presentation, BLS was in the "final stages of extracting and tabulating" data for HHS, reported Mr. Wiatrowski. In lieu of that data, he provided the following results from the 2008 NCS (additional information, he said, is available on the BLS website[14]):

- 99 percent of plan participants had coverage for hospital room and board charges
- 67 percent of plan participants had coverage for hospice care
- The median deductible was $500 per individual per year[15]
- The median co-payment for a physician office visit was $20 for a fee-for-service plan and $15 for health maintenance organization (HMO)

Results showed considerable variation in the incidence[16] and cost of health benefits, particularly based on industry and establishment size. In contrast, there was little variation in covered health services and plan limits. Dr. Selby asked Mr. Wiatrowski and Dr. Piacentini to clarify the variance in cost of health benefits. Mr. Wiatrowski noted that cost of benefits is both a function of the percentage of workers who are covered and the generosity in

[14] U.S. Bureau of Labor Statistics. *National Compensation Survey* available at http://www.bls.gov/ncs/ (accessed February 8, 2011).

[15] In plans that impose an overall plan deductible (where the deductible varied based on the provider, the median was $350 for preferred providers and $750 for out-of-network providers).

[16] That is, who has the health insurance available to them from their employer and what percentage of workers who have it available actually participate in the plan.

terms of covered benefits, and Dr. Piacentini added that their research shows a wide dispersion in premiums yet a similarity in actuarial value of plans. Although they have not investigated in sufficient detail to be able to attribute the differences to specific factors, he expects geography, and the risk characteristics of the employed group to be contributors.

Data Limitations

Mr. Wiatrowski acknowledged that capturing data from plan documents provided on a voluntary basis limits the information BLS can provide to HHS. Of the categories of additional services HHS asked BLS to investigate, "a number" of these, Mr. Wiatrowski said, could not be reviewed because the plan documents contained insufficient information.

Mr. Wiatrowski said, though, that BLS is interested in whether the approach of abstracting from plan documents adequately meets the IOM committee's needs for assessment of what is "typical" for employers or if different data would assist in updating the EHB.

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3

Purchaser Perspectives on the EHB

Health insurance purchasers at the workshop, including Ms. Jerry Malooley, speaking on behalf of the U.S. Chamber of Commerce; Mr. Michael Turpin from USI Insurance Services; and Ms. Helen Darling from the National Business Group on Health (NBGH) stressed the need for flexibility in the essential health benefits (EHB) package and expressed a strong desire to limit the comprehensiveness of the package. The more expansive the package, these panelists said, the greater the cost.

PRESENTATION BY MS. JERRY MALOOLEY, U.S. CHAMBER OF COMMERCE

While Ms. Malooley directs benefit program health policy for Indiana's state employees, on this panel, she spoke on behalf of the U.S. Chamber of Commerce, which represents a continuum of small to large employers. Employers, she said, want to offer health benefits to their employees. Such benefits show appreciation to employees and highlight that the employer values the well-being of its employees. "This, we hope," she said, "translates into loyalty, job performance, and less turnover." At the same time, however, employers must consider the cost of providing these benefits alongside wages, growth, and the competitive environment. Overall, Ms. Malooley stated, employers should be permitted the flexibility to offer coverage that both meets the needs of a broad population and is cost-effective.

Ms. Malooley began by acknowledging that "we all know that for every health product on the market, someone considers it a need and wants insurance to cover it." Consequently, any discussion of what constitutes the EHB package will be controversial. Ms. Malooley stressed, though, that decision makers should remain "objective and vigilant" when determining the package.

In September 2010, the Chamber of Commerce polled 590 small businesses[1] and found that "the definition of essential benefits must not be viewed in a vacuum." In presenting some results of that poll, Ms. Malooley asked the committee to view the EHB package as a minimum floor and to allow businesses to have the opportunity to build on those benefits, particularly considering small employer views as a result of passage of the Patient Protection and Affordable Care Act (ACA),

[1] The poll included 590 small businesses with up to 199 employees. Of those who responded, 57 percent of businesses employed 5-49 employees, 19 percent employed 50-99, and 25 percent employed 100-199 (U.S. Chamber of Commerce, 2010).

- 45 percent of businesses are less likely to hire new employees; and
- Only 29 percent are confident about adding new employees and investing in their businesses (U.S. Chamber of Commerce, 2010).

Comprehensiveness vs. Affordability

To illustrate the complexity of balancing comprehensiveness and affordability, Ms. Malooley posed a question to the committee: When does one person's need to have some new or traditionally non-covered procedure paid by insurance outweigh the majority's need to keep premiums affordable? The desire to offer the most comprehensive benefits may not be worth the loss of affordable coverage.

The definition of the EHB, she said, is "critical" because:

- It will affect employers by establishing the floor for what plans and exchanges must offer and establishing which employer-sponsored benefits will be prohibited from restricted lifetime or annual limits. These considerations will determine the cost of plans.
- It will limit the options available to consumers. If the "floor" is an extensive, expensive benefit package, plans will become very costly and therefore fail to meet the needs of most consumers. Many employers and consumers prefer a more "bare bones plan" and the moderate price it affords. "It would be a mistake," Ms. Malooley said, to curtail flexibility on the part of employers and consumers "by requiring all plans to cover a 'soup to nuts' benefit package."
- An expansive definition will likely force small employers to stop offering coverage. "We do not want the cost of these plans to force employers to stop offering health care coverage to their employees," Ms. Malooley stated.

It has been observed that there is a higher utilization rate for covered services (IOM, 2001). Furthermore, she continued, while utilization has positive effects on individual and population health if the covered services are beneficial and necessary for the individual's circumstances, coverage can also have needless cost implications if unnecessary care is delivered. Thus, employers need freedom, Ms. Malooley said, to direct the content and utilization of benefits.

The Effect of State Mandates on Premiums

State-mandated benefits all "critically affect" the rise in premiums across the states, Ms. Malooley argued, such as those that cover marital and family counseling, contraceptives, and care by specific providers (e.g., acupuncturists, athletic trainers, massage therapists, and pastoral counselors) (CAHI, 2010). While an individual mandate may have a small impact on premiums, when these mandates accumulate, costs aggregate and "premiums really rise." As states add additional benefit mandates, the "base" cost of a plan rises. Iowa, for instance, has 27 mandates, which she stated raises the base cost of a plan by 13 percent. Figure 3-1 illustrates how mandates can contribute to higher costs.[2]

This effect is significant, Ms. Malooley noted, because experience has shown that when premiums increase, more people drop or decline coverage (Chernew et al., 2005; Goldman et al., 2004). Thirty states now require fiscal analysis before the implementation of mandates (Bunce and Wieske, 2010), and at least 10 states offer a "mandate-light" program for people who feel they do not need certain mandated benefits (Bunce and Wieske, 2010).

Nothing precludes a state from requiring additional benefits beyond the EHB. "That is an issue," she said, because the federal subsidy provided to individuals will not account for "how rich the benefit plan is and what the premiums are" for state-added benefits. Consequently, states will assume the additional cost of these state-specific mandates and make payments to individuals to defray the cost of these additional benefits in public programs.[3]

[2] See further discussion of the full and marginal cost of state mandates in Chapter 4, Dr. Cowdry.

[3] Patient Protection and Affordable Care Act of 2010 as amended. Public Law 111-148 § 1311(d)(3)(B)(ii), 111th Cong., 2d sess.

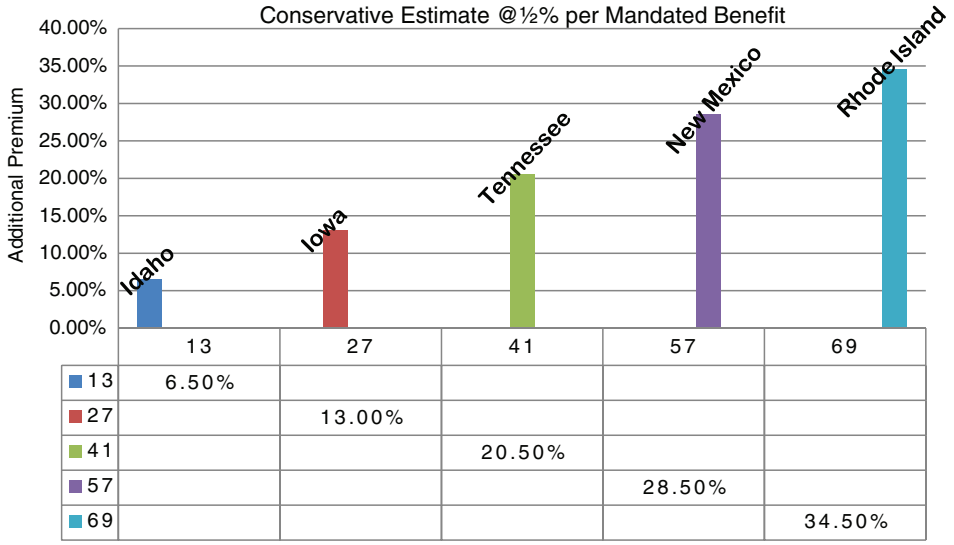

FIGURE 3-1 Insurance premiums can rise as state-mandated health benefits accumulate.
SOURCE: Malooley, 2011. Adapted from data in Bunce and Wieske, 2010.

PRESENTATION BY MR. MICHAEL TURPIN, USI INSURANCE SERVICES

As a speaker knowledgeable of small and mid-sized employer needs, Mr. Turpin, Executive Vice President and National Practice Leader of Healthcare and Employee Benefits agreed with Ms. Malooley that employers want to offer health benefits as a means of attracting and retaining employees. He also emphasized that small and mid-sized employers will decrease or stop offering health benefits if the EHB package is too rich or not designed to drive market-based reforms.

Over the past five years, insured employers with fewer than 100 employees experienced annual double-digit health care cost growth.[4] These increasing costs, he said, resulted from "supply-side components" including increasing physician costs, inpatient facility costs, outpatient facility costs, and prescription drug costs (Engdahl-Johnson and Mayne, 2010). The double-digit growth rates are normally "mitigated," Mr. Turpin said, by reducing plan design and by cost-shifting to employees through higher co-pays, co-insurance, and deductibles. Towers Watson data show that between 2005 and 2010, employer costs for an individual policy rose 28 percent ($6,169 to $7,920) while employee cost sharing has increased over 40 percent ($1,642 to $2,292) (Towers Watson, 2009).

Mr. Turpin described current employer plans as "driven by access, not affordability." Small employers have disproportionately chosen to increase cost sharing rather than to reduce access to a network of specified providers or to centers of excellence. Medical trends have not moderated as they would if network access limitation became the catalyst for outlier facilities to lower costs to be more consistent with more cost effective and equally high quality competitors. Compass Health Analytics, Inc., a private, non-profit consumer data management company, reports how approved provider MRI costs can range from $442 to $1,093 within the same PPO (preferred provider organization) network (Compass Professional Health Services, 2011).

[4] Annual pooled trend and yield averages shared annually by insurers for businesses of different sizes. USI Insurance routinely requests and compares annual trend factors for insured businesses each year to gauge medical inflation and underwrite expected cost increases—independent of the insurer. Data is compiled through an analysis of USI's own book of business, insurers, and the subset of employers who respond to a variety of surveys. Personal communication with Michael Turpin, USI Insurance, August 15, 2011.

Aligning Incentives

Many employers are concerned about an EHB package that will be "too generous," and believe that a "basic" level of benefits would help reduce cost growth. Most of USI Insurance's clients recognize that the current health care system is designed to treat rather than prevent chronic illness. As a result of "misaligned incentives," plan design is the only lever employers can pull to manage their costs. Mr. Turpin acknowledged, though, that the ways in which employers usually manage plan costs (e.g., rationing plan design, increasing co-pays, and increasing deductibles) can inadvertently create barriers to care and ultimately increase long-term costs by limiting access to preventive procedures that could control an individual's chronic illness.

Many small and mid-sized employers, Mr. Turpin said, "are gravely concerned" that the EHB will be designed to require more generous levels of benefits while "doing nothing to change the underlying cost drivers." Without changing cost drivers, generous benefits will only contribute to higher rates of utilization and cost inflation. Employers, he noted, believe "strategy should drive structure." The structure of the EHB should aim to improve health status and better manage chronic illness, which will also serve to "achieve affordable care."

He cautioned that starting with a rich package would "commit the cardinal sin of letting structure drive strategy" because the benefits package would be unaffordable at the outset. In addition, he said that open-access preferred provider organizations (PPOs) and lack of care coordination through primary care providers have resulted in unsustainable medical utilization and an unrealistic expectation from employees that "access means quality." As a result, "there is increasing openness" to the use of "medical homes" as a way to transition from a system focused on treatment to one focused on "rewarding prevention." Employers are uncertain, however, if the EHB package will enable or preclude this transition to medical homes.

Shared Responsibility on the Part of Employers and Consumers

Small and mid-sized businesses are "uninformed" as they have little knowledge of their own employees' health benefit claims—"most feel trapped in pooled risk arrangements." Consequently, these employers have little incentive to engage their employees in wellness activities because their claims are pooled with higher risk employers who have "rich plans and unengaged employees." Mr. Turpin believes legislation should be considered to require the release of paid and incurred employer claims data to help employers better understand population health information. Precedent has already been set in Texas under House Bill 2015 which requires release of data down to two covered lives[5] (Mr. Turpin believes two lives is a bit extreme and that 50 covered lives would be sufficient). In addition, he said, states should encourage the development of self-insured alternatives that allow employers with more favorable claims and cost management strategies to directly benefit from their own efforts.

Essential health benefits can be designed, Mr. Turpin argued, "to get individuals to engage more and for employers to actively participate in engaging in the population health of their employees and trying to drive a healthier lifestyle." Figure 3-2 shows a continuum of "consumer activation" that ranges from healthy individuals to those who are chronically and catastrophically ill. The EHB must consider that every insured person exists somewhere along this continuum and benefit design should reduce barriers to care and drive improved consumer engagement. For example, the EHB should aim to promote identification of those individuals who are asymptomatically ill. Statistically, an alarming number of catastrophic claimants are revealed to have not filed a single claim in the 12 months preceding a catastrophic medical event. Primary care, mandatory screening for key risk factors, and incentives to engage in wellness activities will activate consumers and reduce gaps in care (ICMA and CIGNA, 2008; U.S. Corporate Wellness, 2011). Mr. Turpin noted, though, that individuals must be committed to their own personal health improvement. Additionally, if "we want to reach individuals who are chronically ill and make them stable, we need to reduce barriers to care for certain common chronic illnesses prevalent in certain populations."

[5] Texas HB 2015 (June 15, 2007).

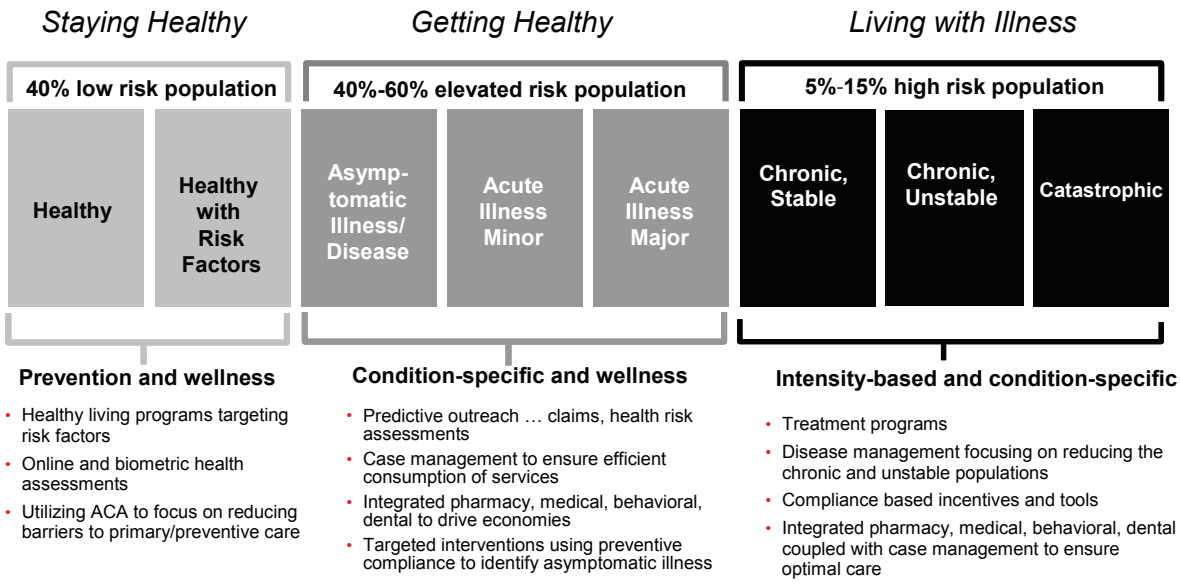

FIGURE 3-2 Insurers use a continuum of patient risk factors to guide consumer engagement efforts.
SOURCE: Turpin, 2011. Reprinted with permission by Sam Ho, committee member, and Executive Vice President and Chief Medical Officer, UnitedHealthcare.

PRESENTATION BY MS. HELEN DARLING, NATIONAL BUSINESS GROUP ON HEALTH

As president and CEO of an association of large employers, Ms. Darling began by urging the committee to focus not only on the goals of providing comprehensive coverage and promoting evidence-based, effective care, but also on the "equally important triple financial goals" of assuring people affordable coverage, protecting them from catastrophic financial losses when faced with serious illness, and helping them avoid unnecessary costs. She proceeded to describe the perspectives and concerns of large employers, including that they should be permitted and encouraged to provide flexible options to their employees, a point, she said, that is built into the ACA. It is very important, she said, that the EHB "be set up in a way that allows for flexibility and also allows for evidence to be constantly created and used in a feedback loop to what is being considered the floor." The "minute the government" defines the package, the benefit floor will be established and will "become the pressure point in every way," she argued.

Committee member Mr. Koller asked Ms. Darling to explain the connection between the committee's work and the decisions made by large self-insured groups. She replied that the ACA outlines broad categories of care. Let's take a category like rehabilitation services; what will be in the EHB should not be just anything that might be considered rehabilitation services. Thus, questions remain as to whether rehabilitation is more specifically going to be set to a maximum of 60 visits or to only visits that restore function. Self-insured employers, she said, make these kinds of decisions "all the time." Generally, if a service is prescribed or ordered by a licensed physician, the service will be paid for unless the employer specifically sets upfront limits or if the service is considered investigational and experimental.

Using Evidence to Evaluate Effectiveness

A properly structured learning health care system[6] "will enable continuous assessment of actual effects on patients and change what might be considered essential benefits, or at least the circumstances in which they would be considered essential," Ms. Darling said. She cautioned that "it is really hard to take things away" but noted that "when there is compelling data that something is downright harmful under certain circumstances, the public actually stops doing it" (e.g., hormone replacement therapy for women, autologous bone marrow transplant for breast cancer, and clinically inappropriate use of Vioxx). An EHB package, then, should support effective, efficient care while also "weeding out" unnecessary and wasteful care. The NBGH recommends, she said, that the committee heavily weigh demonstrated evidence and a track record for clinical effectiveness as a criterion for the EHB package.

Ms. Darling referred to academic studies that have found that a third of U.S. health care dollars are wasted (Kelley, 2009) as reason to support an EHB package with demonstrated evidence of clinical effectiveness. These wasted dollars, she said, are spent on unnecessary, redundant, and ineffective care, all of which should be excluded from the EHB package. "We need a constant process of evidence generation and feedback," she said, to manage care and benefit design in a way that ensures patients are protected from wasteful and harmful practices.

She suggested the committee recognize the tools and resources used by employers and plans for care management and benefit design. Where evidence warrants, employers and plans routinely use care and medical management tools (e.g., step therapy, limits, radiology management) to promote effective care. Step therapy encourages providers and patients to utilize proven effective drugs that are less costly or risky to patients' health than new "blockbuster" drugs that may have less evidence. In addition, dental plans use a combination of limits—annual, frequency, age, and tooth structure—to provide low-cost dental coverage for Americans. This plan design, Ms. Darling said, has improved oral health, prevented overutilization, and minimized the cost of providing oral health care. Less than 3 percent of Americans reach their annual dental limits (NADP, 2009). Furthermore, plans use radiology management programs to ensure patients receive appropriate screenings and that patients are not subject to excessive radiation exposure or unnecessary scans. Studies have found that up to 50 percent of diagnostic imaging is redundant and may lead to unnecessary radiation exposure, particularly for children and pregnant women (AHIP, 2008; Brenner and Hall, 2007; Dehn et al., 2000).

Ms. Darling noted that "by placing high importance on proven clinical effectiveness, the IOM will ensure that patients receive the highest value, safest, and most medically appropriate health care services to meet their individual needs." This focus on clinical effectiveness will also help plans balance comprehensiveness and affordability. Finally, it will create "synergy" between the efforts of employers and plans and the efforts of the government to promote evidence-based benefit design.

Criteria for Effectiveness

To make coverage decisions, Ms. Darling said, employers and plans often use medical necessity along with several other criteria of effectiveness, including:

- Clinical appropriateness of the service setting;
- Sufficient evidence of clinical effectiveness of the service;
- Sufficient evidence of meaningful clinical utility;
- Comparative effectiveness of the service to alternatives;
- Comparative cost and actuarial valuation of the service to alternatives;
- Demonstrated performance and quality of the providers; and
- Individual eligibility criteria (e.g., Herceptin for patients who meet genetic profile, disease state, and treatment history criteria; BMI ≥ 40 for metabolic surgery).

[6] The IOM is currently undertaking a consensus study on the learning health care system, seeking to foster "the development of a learning health care system designed to generate and apply the best evidence for the collaborative health care choices of each patient and provider; to drive the process of discovery as a natural outgrowth of patient care; and to ensure innovation, quality, safety, and value in health care" (IOM, 2010).

Ms. Darling stated that the opportunity to individually apply criteria to specific types of cases is necessary because "you cannot just have a flat benefit. You cannot just say we are going to pay for physical therapy on an unlimited basis, because then everybody would get physical therapy on an unlimited basis, and the system would give us probably two or three times what we would find beneficial." Furthermore, personalized medical therapies are being developed that should apply to specific types of cases; these would not, she said, be considered discriminatory under the required elements for consideration. Comparative effectiveness research will "provide us with very valuable information about how to fine tune" coverage decisions.

Medical Management Practices

Ms. Darling outlined management practices used by employers to promote efficiency in benefits. Employers of all sizes, she said, are provided these resources by their health plans through their insured package of services. She advised the committee that efficiency is an important criterion to consider when designing the EHB package. Coverage, she said, can promote efficiency by requiring "best management practices" to keep benefits affordable:

- **Evidence-based benefits:** An evidence-based benefit model links coverage to the effectiveness of treatments. Cost sharing, provider selection, and plan payments can be used to support evidence-based care and discourage ineffective care. For example, by reducing or eliminating co-pays for maintenance drugs (e.g., for diabetes, asthma, and hypertension) with a strong evidence base for effectiveness, the employer's plan design can encourage patient adherence to drug regimens.
- **Targeted evidence-based preventive care:** To improve health and reduce long-term costs, employer plans can provide incentives such as "first dollar coverage" (i.e., little or no co-payment) for evidence-based preventive care services for targeted populations. Education programs to improve employees' awareness of preventive care are just one example.
- **Emphasize primary care:** Employers are often willing to pay more for primary care coordination and patient management, for example, by choosing providers who incorporate the "advanced medical home concept."
- **Meaningful cost sharing:** Employers set cost sharing at levels that reduce excessive and inappropriate utilization but ensure access to needed, appropriate medical care by, for instance, varying cost sharing based on clinical necessity and therapeutic benefit. Employers have reduced cost sharing when plan participants use evidence-based care such as using decision supports and participating in disease management programs.
- **Prescription drug management:** Employers manage prescription drug use and pharmacy spending by establishing preferences for select generics and brand-name drugs. Step therapy, generic substitution requirements or incentives, generic education programs for plan participants and physicians, a separate deductible for prescription drugs, preauthorization for selected drugs, reduced cost sharing for mail order compared to retail purchase, mandatory mail order of maintenance medications, tiered co-payments, co-insurance rather than co-payments for medications, dose optimization, and quantity-duration protocols for certain medications are all used to manage prescription drug costs.
- **Health improvement programs:** Employers offer incentives such as premium discounts to plan participants who engage in health improvement programs and adopt healthier lifestyles.
- **Targeted disease management programs:** Employers provide targeted, evidence-based disease management programs for certain chronic and potentially high-cost conditions. Employers use incentives, rewards, and premium discounts to encourage participation.
- **Retail/convenience care clinics:** To add convenience and reduce inappropriate emergency room visits, employers offer access to retail clinics for common, basic medical services. Employers promote services at retail clinics through education campaigns and by lowering co-pays for retail clinic services.
- **Consumer decision-support tools:** Employers offer decision-support tools (both during plan selection and at point-of-care) to help plan participants make informed decisions about their health. These tools

include customized comparison and financial modeling to help people choose among plan options; hospital and physician report cards to assess provider performance against evidence-based standards; and nurse lines, self-care guides, self-study modules, online information, health coaches, health advocates, and consumer medical information services. Some employers require that plan participants use decision-support services before nonemergency surgery.

- **Pay-for-performance:** Employers link plans' provider payments to health care quality, paying more for better outcomes, greater efficiency, and better performance on prevention, chronic care management, and patient satisfaction measures. Employers also provide financial incentives to plan participants who choose better performing providers, for example, by offering a preferred tier of medical groups and hospitals with differential co-pays based on performance in quality and costs.
- **High-performance networks:** Employers use high-performance networks to reduce costs and improve quality by offering specialized services through facilities that meet criteria for volume and clinical outcomes, patient and family-oriented services, and evidence-based medicine.
- **Health information technology (HIT):** Employers require health care vendors to use interoperable HIT wherever possible or provide personal health records for plan participants.
- **Transparency (cost and quality):** Employers require plans and providers to publicly disclose information about the price and quality of care.

The focus on primary care prompted committee member Dr. Santa to ask Ms. Darling to comment on the degree to which the effectiveness of primary care vs. more specialty care is considered by employers as a part of benefit design. This emphasis on primary care, she said, is based on evidence comparing systems with primary care as the foundation (Starfield et al., 2005) and evidence showing that primary care encourages ongoing patient-provider relationships, which may, among other things, decrease duplicative testing. Ms. Darling said that NBGH has been working with employers and plans to "build in more reasons for starting with primary care" such as having the employee pay less for primary care visits. IBM, for example, has eliminated co-pays for primary care.

Limiting State Mandates

Ms. Darling concluded by suggesting that because state mandates are often driven "by forces that sometimes have very little to do with evidence and very little to do with cost considerations," the committee should not consider state mandates as a criterion for the EHB package. There is a lack of awareness of the collective costs of mandates. It is important for the committee to "fully grasp the significant cost impact of overly comprehensive or open-ended coverage."

In sum, she said, the EHB package has to be something that rules some things out; something between everything under the sun and a very narrow, limited package. Thus, she said, the committee and the U.S. Department of Health and Human Services should aim to ensure affordable but comprehensive coverage.

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4

State Experiences with Defining a Minimum Benefit Standard

Some states, including Massachusetts, Maryland, and Utah, have state-specific approaches to defining minimum benefit packages for the individual and employer markets that may provide important lessons for defining essential health benefits. Economist Dr. Jonathan Gruber discussed the economic principles underlying definition of benefits and described lessons from Massachusetts' experience with health reform. These lessons were expanded upon by Dr. Jon Kingsdale, formerly of the Massachusetts Commonwealth Health Insurance Connector Authority. Then, Drs. Beth Sammis and Rex Cowdry of the Maryland Insurance Administration (MIA) and Health Care Commission (HCC), respectively, described Maryland's process for developing a "standard benefit plan" in the mid-1990s. Next, Representative James Dunnigan of the Utah State House of Representatives and, finally, Mr. Matt Salo of the National Governors Association (NGA) urged the committee to recognize the need for state flexibility in definition and implementation.

PRESENTATION BY DR. JONATHAN GRUBER, MASSACHUSETTS INSTITUTE OF TECHNOLOGY (MIT) AND THE NATIONAL BUREAU OF ECONOMIC RESEARCH (NBER)

As a founding member of the Massachusetts Health Insurance Connector Authority Board, and as an advisor to Congress and the Obama administration during the development of the Patient Protection and Affordable Care Act (ACA), Dr. Gruber focused on the tradeoffs inherent in developing the essential health benefits (EHB) package: generosity of coverage, affordability of coverage, and minimizing disruption from current insurance status.

Generosity of Coverage

Dr. Gruber noted that "we would all like to include the benefits we think are part of a real and generous insurance package." Despite this desire for generosity, to ensure affordability, coverage is subject to (1) specified categories of care, (2) limitations, and (3) cost sharing.

Categories of Covered Benefits

The list of the essential health benefits in Section 1302 is, Dr. Gruber said, "a fundamental change in the nature of insurance coverage in America. Never before have we mandated such a comprehensive set of insurance

benefits." Although some categories of care are mandated, many benefits (e.g., infertility treatment, chiropractic care, subspecialty care) are not specified. Dr. Gruber's experiences, he said, imply that the committee can expect to "hear from advocates, all with compelling arguments about important things to include." The committee and the U.S. Department of Health and Human Services (HHS) will need to make difficult decisions about how or whether to "go beyond the list" of categories included in the ACA.

Dr. Gruber reminded the committee that the ACA already eliminates annual and lifetime limits and requires maternity, mental health, habilitation, and pediatric vision and dental coverage. Such benefits, he noted, are not part of typical employer plans. The issue, he asked the committee, "is how much further do you want to go?"

Limitations on Coverage

Although the ACA prohibits annual and lifetime limits on coverage, it does not "rule out more specific limits," such as limits on the number of mental health or physical therapy visits, or step therapies (e.g., requiring certain prescription drug regimens such as starting treatment with a generic drug). Consequently, Dr. Gruber said, HHS will have to address "the extent to which it wants to allow these sorts of limits on coverage or the extent to which it wants to say, 'if a benefit is covered, it must be covered in an unlimited fashion.'" Moreover, decisions about one set of benefits can have repercussions for others. For example, the cost of adding a certain prescription drug benefit may vary depending on the extent of allowable mental health coverage because increased mental health coverage is associated with increased use of prescription drugs to treat mental illness.

Patient Cost Sharing

Dr. Gruber pointed out that the ACA provides relatively little guidance on cost sharing other than limiting the deductibles for small businesses and instituting out-of-pocket (OOP) maximums that are a function of income. The committee could decide, he said, to "make decisions" or "remain silent" about issues of cost sharing. For example, the committee could decide to advise the Secretary to have a maximum deductible for individuals, co-insurance not more than a specific amount, or co-pays not more than a specific amount. The committee could also advise the Secretary on the nature of cost sharing. In particular, Dr. Gruber suggested the committee consider providing guidance on "what the out-of-pocket maximum applies to" because the ACA does not "go into enough detail" (i.e., does it apply to everything in the insurance package). He advised the committee to have a broad OOP maximum if the idea is to protect people.

Committee member Dr. Santa commented that the ACA's variation in OOP maximums by income is "an unusual aspect of benefit design" that may "create selection issues since health status tends to vary with income." Dr. Gruber noted, however, that it is unlikely that people will strategically work harder to change their OOP maximum, so selection is not a "significant issue." The variable OOP maximums, he noted, are "really about protection" from high costs as a function of income. West Virginia's state employee plan, for instance, has a similar feature in which OOP maximums vary by income (Public Employees Insurance Agency, 2011).

Actuarial Value

Dr. Gruber briefly explained the concept of actuarial value to the committee and audience. Four levels of coverage are stipulated in ACA—bronze, silver, gold, and platinum—and each has differing actuarial values that reflect how much of the cost is borne by the insurer and how much by the patient.[1] The silver tier of plans specified in the ACA has an actuarial value of 0.7, he said. This means that on average, across all of the people within the silver tier plan offered by an insurer, the insurer must cover 70 percent of the cost. In other words, for a healthy person who utilizes few services, the insurance company would cover very little because the person has not yet met the required deductible. For a sick person who incurs high medical costs, the insurer may cover close to 100 percent because the patient has considerably exceeded the personal OOP maximum. The actuarial values, he said in

[1] Patient Protection and Affordable Care Act of 2010 as amended. Public Law 111-148 § 1302(d)(1)(A)-(D), 111th Cong., 2d sess.

response to an inquiry from committee member Dr. Selby, are based on a "given standard population" that could in reality look like the employer-sponsored insurance population or the uninsured, depending on who enrolls. The law appears to give insurers a lot of latitude in the ways in which they could achieve the various actuarial levels.

Affordability of Coverage

There is a fundamental tension, Dr. Gruber stated, "between our desire to make insurance as generous as possible and a desire to make the [EHB] mandate both moral and feasible by making health insurance affordable." The more benefits included in the benefits package, the more expensive the package becomes, which in turn makes health insurance less affordable, causing people to opt out of coverage. The ACA's mandate to buy health insurance, Dr. Gruber said, comes with an obligation to make health insurance affordable. Gruber argued that the tradeoff between cost and coverage should be the committee's principal consideration and that actuarial analysis would help in making these decisions.[2]

The Consequences of Raising Costs

A Congressional Budget Office (CBO) analysis suggests that the ACA will cost approximately $950 billion by 2019 if the EHB package is comparable to an average employer-sponsored insurance plan. Of course, he said, if the package "gets more generous," costs will rise with a variety of possible impacts. For instance, the individual mandate clause stipulates that if individuals would have to pay more than 8 percent of their income for health insurance, they are not subject to the mandate.[3] A more generous, and thus more expensive EHB package, would therefore lead to more individuals eligible for exclusion from the mandate.

Furthermore, the financial exposure of individuals receiving federal subsidies to purchase insurance will be capped at a percent of their income; in these cases, the government is the residual claimant in that the government bears the additional costs of making the benefit package more expensive. Conversely, for individuals ineligible for federal subsidies (i.e., for individuals above 400 percent of the federal poverty level [FPL]), the individual policyholder is the residual claimant. Dr. Gruber highlighted this distinction because it shows who will face "the extra cost" of making the EHB package more expensive.

To consider the cost impact of coverage decisions, Gruber developed a micro-simulation model that he described as "calibrated to match what CBO produced for the score of the ACA" (Long and Gruber, 2011). To give the committee a sense of the implications of its recommendations, he used an extreme example: if the committee recommended an EHB package that raised the cost of insurance by 10 percent above the CBO's estimate, government costs would rise by 14.5 percent.[4] Additionally, this 10 percent increase in costs would erode the effectiveness of the insurance mandate: uninsurance would increase by 4.5 percent (approximately 1.5 million fewer people would be insured than if the committee had recommended an EHB package that cost 10 percent less). The fundamental tradeoff, then, is that making the EHB package more comprehensive undercuts the gains that could have been made by the ACA.

Minimizing Disruption

In addition to considering the tradeoff between comprehensiveness and affordability, Dr. Gruber suggested the committee consider minimizing disruption. "You are not just setting up a benefits package for people who used to be uninsured," he said. "You are also setting up a benefits package for people who have insurance and by and large like it." He reminded the committee that during the health reform debate, some politicians promised that "if you like your plan, you'll be able to keep it" (The White House, 2009). There is a wide variance, though, in existing plans. Some people have very limited coverage (i.e., mini-med plans that only cover $100 a day in

[2] The IOM committee was not given resources for actuarial analyses.
[3] § 1501(e)(1)(A).
[4] This is more than 10 percent because of the government being the residual claimant.

the hospital), while others have more generous coverage. If the EHB package is more generous than a typical employer-sponsored plan, it is going to raise costs and cause people to have to "buy up" from what they are currently happy with. Therefore, the committee should be aware, he said, of the political considerations involved in its decisions, including whether this variation in plans should "be allowed to continue."

Lessons from Developing "Minimum Creditable Coverage" Requirements in Massachusetts

Dr. Gruber explained the "minimum creditable coverage" mandated by the Massachusetts legislature. He defined minimum creditable coverage as "the minimum level of coverage that people could hold and still meet the individual mandate." He provided four examples to illustrate some of the issues the Commonwealth Health Insurance Connector Authority Board faced when developing the minimum creditable coverage requirements: removing lifetime limits, removing annual limits in the young adult plan, mandating prescription drug coverage, and providing maternity coverage for dependents.

Removing Lifetime Limits

Dr. Gruber explained his argument in favor of prohibiting lifetime limits. Economic principles, he said, made it clear that "real insurance does not have a lifetime limit," and "it seemed to me to make no sense to say if someone is incredibly sick, we are now cutting you off because you have achieved the limit." The Connector Board, though, received volumes of data from insurance companies and unions, among others, showing that limits keep costs down. Furthermore, state policy makers intended the law[5] to be "about covering the uninsured not telling insurers they had to change." After much debate, the Connector Board allowed lifetime limits to remain in place.

Removing Annual Limits in the Young Adult Plan

Massachusetts' young adult plan is a low-cost insurance plan designed for the under-26-year-old population. The plan allowed annual limits, which the Connector Board initially believed was "a fundamental problem." Actuarial analysis revealed, however, that removing the $50,000 annual limit would raise the cost of the insurance by 15 percent. When examining this issue, the Connector Board considered that one of the principal aims of Massachusetts' health reform law was to "get young people signed up for health insurance," and as a result, the under-26-year-old population has had the largest increase in the rate of coverage. Furthermore, at the time the Connector Board was evaluating the annual limits, not one young adult had hit the $50,000 limit. The Connector Board has not, to this day, eliminated the limit but will again be considering the issue in light of the ACA's mandate to remove annual limits.

Mandating Prescription Drug Coverage

As Massachusetts was the first state to mandate prescription drug coverage (Reisman, 2008), the Connector Board had to determine what limits should be placed on that coverage. Some plans suggested covering a certain number of drugs each month, while other plans suggested covering up to a certain dollar exposure each month. Using evidence from the Medicaid program, which had recently instituted prescription drug limits, the Connector Board determined that the limits could have considerable health and cost implications. The Connector Board decided to ban "flat limits" on prescription drug coverage, even though the board knew this ban would raise costs. The Board decided, however, to allow insurers to appeal a denial of their prescription drug practices on the grounds that the practices were an innovative way to control cost.

[5] An Act Providing Access to Affordable, Quality, Accountable Health Care. Chapter 58 of the Acts of 2006 of the Massachusetts General Court (April 12, 2006).

Providing Maternity Coverage for Dependents

Dr. Gruber described the question of whether to cover maternity coverage for dependents as "the most daunting political issue the board faced." The issue arose because insurers had to provide dependent coverage, and Massachusetts had mandated the coverage of maternity benefits. A number of organizations in the state (particularly Catholic hospitals) argued, however, that their health insurance plans should not cover maternity benefits for dependents. A very vigorous debate ensued, Dr. Gruber said, and the Connector Board decided that the minimum creditable coverage did need to include maternity coverage for dependents.

Lessons from Massachusetts

The "fundamental lesson to be learned" from these four examples, he said, is that the committee cannot anticipate all the issues that will arise in implementing the EHB package. Therefore, he said, HHS has to make a tradeoff between the rules of coverage imposed and the flexibility created through an appeals process for insurers and employers on what should be in a benefit package. The tighter the rules are, he said, "the more people are going to want to appeal them." While Massachusetts instituted a "very flexible appeals process for insurers and employers," Dr. Gruber cautioned that the process is time consuming and leads to "enormous uncertainty" for employers. Flexibility at the outset, he said, will provide some room for restrictions to get tighter over time.

Dr. Gruber concluded by reiterating that the committee should "start modestly." Additional requirements beyond what are already included in the ACA will add costs to both the public and private sectors and undercut support for the ACA. Moreover, the committee should remember, he said, "that insurance design is dynamic" and that "it is important to set up a process that evolves over time and is flexible to innovation." The Connector Board, he said, is "a learning organization" in that it has a process to revisit issues rather than "imposing" too many restrictions at the outset.

When committee member Dr. McGlynn asked Dr. Gruber what, in retrospect, the Connector Board should or should not have done, he advised the committee that the Connector Board did not incorporate cost estimates enough. Specifically, he said, the board did not "define the target and then have actuaries inform the committee about the tradeoffs inherent" in decisions. Now, he said, the Connector Board discusses options at its meetings, sends those options to actuaries to score, and reconvenes to vote on those options based on the actuarial score. This way, even when a Board member does not agree with the outcome, "it is a fine process."

PRESENTATION BY DR. JON KINGSDALE, WAKELY CONSULTING

Before his current role as managing director at Wakely Consulting, Dr. Kingsdale directed the Commonwealth Health Insurance Connector Authority, an institution delegated by the Massachusetts legislature to determine certain policy issues, including the mandated "minimum creditable coverage."[6] Framing his advice as being "experientially based," Dr. Kingsdale began by identifying three issues for the committee's consideration: (1) defining EHB will be one of the most challenging parts of implementing the ACA, (2) the committee and HHS will have to make its decisions based on a short, highly prioritized list of principles, and (3) the committee and HHS will need to make decisions based on partial information.

Challenges of Implementing the ACA

Beyond the "obvious realities of how controversial and passionate people are about defining benefits," and "the enormous dollar implications both for consumers and payers," Dr. Kingsdale identified a further challenge in defining the EHB: the ACA does not have broad stakeholder support, and the committee "is undertaking its task in a highly divided nation." In Massachusetts, state reform efforts enjoyed "broad political support." Whatever is put into the EHB package, he said, "can be portrayed by opponents of the ACA as unfairly burdening employers

[6] Commonwealth Health Insurance Connector Authority 956 CMR 5.00: Minimum Creditable Coverage. Full text available at http://www.lawlib.state.ma.us/source/mass/cmr/cmrtext/956CMR5.pdf.

or individuals who want a lesser package." On the other hand, proposing a "lesser benefit package" will disappoint some supporters of the ACA and individuals who think that the ACA did not go far enough. Dr. Kingsdale suggested that "overreaching could doom implementation," so the committee should err on the side of being "conservative" about adding to the EHB package.

Suggested Principles for Consideration

Dr. Kingsdale began by explaining what he called potentially "obvious" things about the realities of purchasing health insurance. There is a tendency, he said, to think about benefits in the context of "something someone else will pay for." He noted, however, that "there are real people who cannot afford what we consider to be an ideal benefit package, and they actually have to pay for it in premiums."

Dr. Kingsdale said his experience implementing components of Massachusetts' health reform law,[7] including defining minimum creditable coverage, suggests that there is broader popular and political support of the goal of reform laws, such as the ACA, being "about giving more people decent coverage as opposed to being about raising the standard of coverage." He advised the committee, therefore, that when it has to "make decisions about close calls regarding benefits," it is important to return to this purpose as a guiding principle. Second, he said, the ACA "will live or die on affordability." Most benefits, though, are costly, regardless of notions frequently promulgated that additional benefits save money. Lastly, he said, there is a "fair degree of consensus around the minimum benefits." There are very few benefits beyond those typically covered by commercial insurance that significantly improve population health or reduce costs.

Decision Making Based on Partial Information

Dr. Kingsdale concluded by sharing what he believed the committee could learn from the Massachusetts experience. Massachusetts did not mandate its minimum creditable coverage stipulations until two years after the law passed. This timeframe eased acceptance and facilitated an orderly transition to implementation. Furthermore, he added, during those two years, his organization learned from employers and insurers about "exceptional cases" that would not fit into a set of minimum creditable coverage requirements. Dr. Kingsdale suggested that the committee similarly phase-in EHB requirements or, at least, consider case-by-case exceptions after the EHB requirements have been instituted. These case-by-case considerations proved to be "very educational" in Massachusetts; they allowed the definition of minimum creditable coverage to evolve. The Connector Board annually revisits the topics raised.

Dr. Santa noted that once covered benefits are determined, there are other important variables to consider, including utilization, price, and quality. Once benefits are determined, he asked, "how much of the problem is solved?" In answering, Dr. Kingsdale recalled the issue of dependent maternity coverage raised by Dr. Gruber. The "tough questions" in this case, he noted, "are not cost implications" or related to scientific evidence. When Dr. Santa asked Dr. Kingsdale if his agency considered the costs of coverage against the rates of caesarean sections, adverse events, and the price of delivery at a hospital, Dr. Kingsdale replied that the "larger issue" was the perceived "imposition of management decisions" on employers "who felt they offer perfectly good health benefit packages."

PRESENTATION BY DR. BETH SAMMIS, MARYLAND INSURANCE ADMINISTRATION (MIA)

Dr. Sammis, Acting Insurance Commissioner, began by stating that in a previous role, she was intimately involved in the development of a standard benefit plan in Maryland. This plan, which is called the Comprehensive Standard Health Benefit Plan (CSHBP), was developed by the Maryland Health Care Commission (MHCC) after the Maryland Health Insurance Reform Act of 1993 mandated that all carriers participating in the small employer market must sell the CSHBP to any small employer who applied for it. The objective of the law, Dr. Sammis said, was to allow small employers to be better able to compete with large employers in the state, including the federal

[7] An Act Providing Access to Affordable, Quality, Accountable Health Care. Chapter 58 of the Acts of 2006 of the Massachusetts General Court (April 12, 2006).

government, by providing small employers with access to affordable, comprehensive health plans for employees. The standard also facilitated comparison of benefit plans. The CSHBP had to (1) be actuarially equivalent to the minimum benefits required to be offered by federally qualified HMOs and (2) have an average premium that did not exceed 12 percent of Maryland's average annual wage. These standards guided the development of the CSHBP by establishing a "floor" and "ceiling" for benefits. Dr. Sammis noted that the legislature allowed the Health Care Access and Cost Commission (now the MHCC) to exclude state-mandated benefits from the CSHBP and required the Commission to consider the benefit plans provided by large employers in Maryland.

Process of Determining Benefits

The task force created by the Commission to design the CSHBP began by examining 70 policies submitted by carriers and employers in Maryland and choosing eight representative policies. Using these representative policies, the task force developed a list of "controversial benefits" based on expert opinion and public comment. Next, the task force identified a set of benefit design options, priced these using actuarial analyses, and then again solicited public comment. Throughout the entire process, the task force grappled with the question of "what are essential benefits," as well as what benefits were important to the public and what the role of cost in determining the benefit plan would be. Ultimately, the task force recommended specific covered services, limitations, and exclusions, and the cost sharing for indemnity, PPO, health maintenance organization (HMO), or point-of-service (POS) plans.

Medical Necessity Determination

The CSHBP, Dr. Sammis explained, excludes services and supplies that are not medically necessary. While there is no single medical necessity definition in state law, carriers must abide by statutory medical necessity determination standards. These standards are that medical necessity protocols must be objective, clinically valid, compatible with principles of health care, flexible, and abide by standards promulgated by accrediting bodies (i.e., the National Committee for Quality Assurance [NCQA] and Utilization Review Accreditation Commission [URAC]). Every carrier in Maryland, including those outside the small group market, is required to file its utilization review plan and criteria with the MIA.

When an individual's request for coverage is denied and then appealed to the MIA, medical experts address whether the criteria used by the carrier to reach its determination meets the statutory standards and were appropriately applied in the specific case. If the medical necessity criteria have not been appropriately followed, the Insurance Commissioner has the authority to order the carrier to pay for the service and to modify the carrier's medical necessity criteria to incorporate the recommendations of the medical experts.

One of the major concerns of carriers arises when a carrier is ordered to change its criteria as a result of an appeal. Carriers perceive that they are put at a competitive disadvantage because other carriers have not been ordered to provide the same coverage despite that they may have a similar noncoverage policy as the carrier that was ordered to provide coverage. For example, Dr. Sammis' department had to determine if because the CSHBP does not expressly exclude coverage for human growth hormone (HGH) for idiopathic short stature (a common exclusion in other market segments), it should be covered when medically appropriate in the small group market. The MIA received a complaint about a denial for HGH for idiopathic short stature for a dependent under a small group policy. The independent review organization determined that HGH was medically necessary in this case and that, more generally, it should be covered under specific circumstances.

As a result, Dr. Sammis has committed to establishing a more transparent process for when a medical expert notifies her that a carrier's criteria are not in compliance with the statutory requirements. That way, when she orders a carrier to modify its criteria, she can notify all of the other health plans in the marketplace. In addition, she is developing a process by which the MIA performs a six-month or one-year review to see whether or not other carriers have, in fact, adjusted their criteria. When prompted by Dr. Selby, Dr. Sammis confirmed that Maryland does not provide guidance on the application of principles of medical necessity to the evaluation of cases. The only specific medical necessity guidance that Maryland has provided relates to when gastric bypass surgery could be considered medically necessary.

When the CSHBP was initially implemented, Dr. Sammis said, the small group market reforms were "quite successful in cost containment" partially because of the "death of indemnity plans." She described Maryland's small group market reform as having "moved the entire market out of indemnity plans into PPO and HMO plans." Although these initial successes in cost containment have not been maintained, Dr. Sammis does not believe this to be unique to the standard benefit plan in Maryland. After all, she said, the CSHBP is the floor, and only about 2 percent of the state's small employers buy this level of coverage, opting instead to buy additional benefits (MHCC, 2007; Wicks, 2002).[8]

PRESENTATION BY DR. REX COWDRY, MHCC

Dr. Cowdry, Executive Director, expanded on Dr. Sammis' review of CSHBP's origins and described how the CSHBP relates to the benefit tiers established by the ACA (see Figure 4-1). He considered planning along two separate dimensions: the breadth of services and cost sharing. Keeping these dimensions separate, he said, is important as the processes for determining cost sharing might differ quite drastically from those for determining the breadth of services offered. In Maryland, for example, when the premium cap for the comprehensive standard plan was reduced from 12 percent to 10 percent of the average wage in the state, the MHCC had to consider whether it should limit benefits or adjust cost-sharing arrangements. The MHCC, Dr. Cowdry said, avoided the difficult decisions necessary to reduce covered services. Although cost sharing was increased to meet the premium cap, the increase had little effect on costs or affordability because "people still purchased riders to create more generous plans with less cost sharing." With the exception of pharmacy benefits, modifying cost sharing rather than reducing benefits has continued to be standard practice. When the MHCC decided to "modernize" CSHBP's rigid three-tiered pharmacy benefit plan to allow for value-based incentives, it created a less expensive core pharmacy benefit that allowed employers to purchase a variety of pharmacy riders at modified community rates.

Lessons Learned

Once benefits are issued, Dr. Cowdry noted, "it is very hard to stop covering services or refuse to pay for them." Additionally, "too much design specificity or standardization prevents" the kind of innovation needed to control health care costs. Greater specificity can interfere with the ability to craft a "sensible" package. The ACA includes cost sharing limits, he said, including a "hard floor" at the bronze level, a subsidy floor at the silver level, and OOP maximums. With these cost-sharing specifications in place," Dr. Cowdry asked, "the question now becomes: should the EHB package only address the breadth of coverage service decisions?" One approach would leave cost-sharing decisions to the states. The EHB package would be based on the broad categories in the ACA, and refined and defined using the contractual provisions of the "typical" employer plan with detailed coverage policies developed by carriers based on evidence of effectiveness and specific cases addressed through medical necessity determinations. This option, he said, "moves with the times" as new evidence "strengthens the way we determine medical necessity" and provides greater uniformity to that process.

Contract Limits

Dr. Cowdry referenced Ms. Helen Darling's testimony (see Chapter 3) to support his claim that some benefits—especially those without clear indications or guidelines—may be better managed with an annual limit on cost or frequency, such as how physical therapy visits have been limited contractually.

Dr. Cowdry suggested that the ACA and other statutes may make it difficult to implement appropriate limits on services based on scientific evidence. For example, the ACA prohibits lifetime limits and phases out annual limits. Additionally, for employers with more than 50 employees, the Paul Wellstone and Pete Domenici Mental Health

[8] The Maryland Insurance Administration also surveyed the largest carriers in 2008 regarding the top five benefit plans sold to small employers. These results were not published.

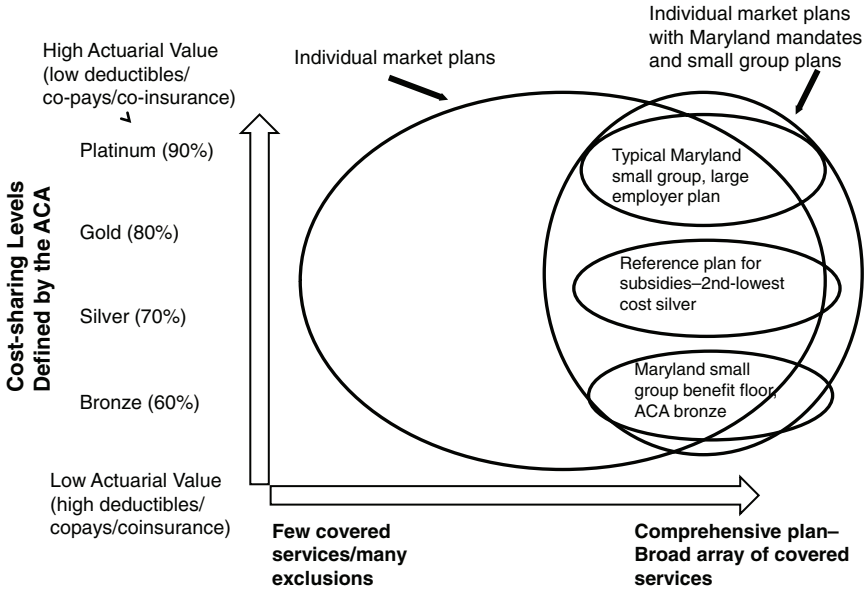

FIGURE 4-1 The benefit categories in the ACA could vary in breadth and depth of coverage.
SOURCE: Cowdry, 2011.

Parity and Addiction Equity Act of 2008[9] prohibits service limits and cost sharing for mental health and substance abuse treatments that are more restrictive than the service limits and cost sharing for most medical-surgical benefits. Dr. Cowdry argued that together, these statutory constraints may make it difficult to craft an appropriate, effective, and cost-effective benefit. For example, for autism he reported that their reviews of the limited evidence available regarding the treatment of autism suggested that intensive interventions from ages two to six offer substantial promise, but Maryland's Attorney General has suggested that a benefit focused solely on those ages and including an annual limit would violate the law. Dr. Cowdry expressed uncertainty about how, given statutory constraints, the use of specific services for specific conditions can be limited through the benefit design process.

Mandate Review Process

Maryland's General Assembly enacted an annual mandate review process that aims to deter the enactment of what Dr. Cowdry called "bad mandates" based on impassioned advocacy rather than good evidence. Although the process is not perfect, he said, it considers evidence of the clinical, social, and financial impact of the mandate. He also described Maryland's quadrennial mandate review process that estimates the costs of all of Maryland's mandates—both the full cost of the covered service and the marginal cost of the mandate (i.e., the incremental cost of benefits beyond those included in a typical, large employer's self-insured plan). Mercer's report to the MHCC indicates that the full cost of Maryland's mandated benefits is approximately 18.6 percent of individual premiums (see Table 4-1) and 15.4 percent of group premiums. However, the marginal cost of these state mandates is only approximately 2.2 percent of group premiums because most of the mandated benefits are already voluntarily available in comparative self-funded plans which are exempt from mandates. If benefits not covered in the small group market (e.g., in vitro fertilization) are not considered, the marginal cost is closer to 1.5 percent (MHCC, 2008).

[9] Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008. Public Law 110-343, 110th Cong., 2d sess. (October 3, 2008).

TABLE 4-1 The Marginal Cost of Maryland's State-Mandated Benefits Is Less Than the Full Cost Per Benefit

Mandate	Full cost as percent of premium–individual market (%)	Marginal cost as percent of premium (beyond typical self-insured large employer plan) (%)
Mental illness, substance abuse	5.9	0.5
In vitro fertilization	1.0	0.6
Childbirth	1.7	0.0
Length of stay for mothers of newborn	2.3	0.0
Child wellness	1.5	0.0
Diabetes equipment, supplies, self-management training	0.6	0.0
Contraceptives	0.7	0.1
Treatment of morbid obesity	1.0	0.2
Smoking cessation	0.5	0.3
Others (each < 0.05%)	3.4	0.5
TOTAL	**18.6**	**2.2**

SOURCES: Cowdry, 2011; MHCC, 2008.

Comprehensive coverage may "be the right place to be" if such coverage can be merged with value-based incentives to patients and providers and a rigorous process to exclude non-medically necessary interventions. State exchanges, he suggested, "can be laboratories for exploring different limits and the kind of cost-sharing designs that make sense."

PRESENTATION BY REPRESENTATIVE JAMES DUNNIGAN, STATE OF UTAH HOUSE OF REPRESENTATIVES

Representative Dunnigan, an insurance broker with Dunnigan Insurance, has served in the Utah House of Representatives since 2003, and as Chairman of the Utah Health Exchange Oversight and Implementation Working Group has been involved in the debate and the development of Utah's health reform law, passed in 2008.[10] He began by noting that he was speaking on behalf of state legislatures across the nation in urging the committee to recognize state differences and the impact of EHB decisions on state budgets.

Recognizing State Differences

Representative Dunnigan suggested that the committee "preserve state flexibility," as the scope of benefits offered in the EHB package will be a "significant factor" in the cost of the qualified health plans (QHPs) offered in insurance exchanges. The ACA, he noted, stated the scope of benefits should be equal to the scope of benefits provided under a typical employer plan, and told the committee that this is "problematic" for states because what is typical in one state may not be typical in another due to state mandates, for example. "To avoid imposing the political choices of each state on 49 others," he said, "the Secretary should allow what is typical to be determined on a state-by-state basis." In the case of a multi-state exchange, what is typical should be determined on a multi-state basis. Furthermore, he recommended that the Secretary allow states to "spell out" the definitional details of the categories listed in Section 1302. In lieu of state specification, he proposed the creation of a three-tiered approach for the EHB package:

- **Tier 1:** limited to those benefits provided under a typical employer plan offered within the geographic boundaries of an exchange.

[10] Health System Reform, H.B. 133, State of Utah General Session (March 2008).

- **Tier 2:** benefits that extend the coverage of a typical employer plan. These benefits would be value-driven and have a strong evidence base. States would elect, on a state-by-state basis, whether to include tier 2 benefits in their EHB package.
- **Tier 3:** any other benefits that a state may wish to include.

Under Representative Dunnigan's plan, exchange subsidies for tier 1 and tier 2 benefits would be fully funded by the federal government and subsidies for tier 3 benefits would be fully funded by the respective states.

Recognizing the Impact on State Budgets

Representative Dunnigan advised HHS to reach out to state insurance commissioners and health department directors to gather evidence on the cost implications for including and excluding certain benefits. Additionally, he asked for consideration of the implications of the EHB package on state Medicaid programs. Each state's Medicaid program uniquely reflects the fiscal capacity and political preferences of the sponsoring state; the Medicaid expansion "will have a direct impact" on state budgets. This impact is especially true once the responsibility for funding the newly eligible persons shifts from the federal government to the states in 2017. At that time, Representative Dunnigan said, states will have to either raise additional revenue or, more likely, divert funding that "would otherwise go to other important services like transportation, corrections, and education." Medicaid has been "competing with and sometimes crowding out other essential government services since its inception," Representative Dunnigan said. The EHB will not apply to traditional Medicaid, but does apply to Medicaid benchmark and benchmark-equivalent programs.

The EHB package could affect any program for which there is mandated coverage, including Utah's purchase of insurance for state employees and the employees of state-funded entities such as school districts and institutes of higher education. As Utah assumes 95 percent of premium costs for the state employees' health insurance plan, EHB determinations will directly impact state costs. The degree to which legislatures will have to either raise new revenue or reduce funding for other essential services or decrease employee compensation will "depend in large measure" on the initial definition of the EHB package, as well as on subsequent revisions of this package.

The implementation of the ACA, Representative Dunnigan said, may result in employers who currently offer coverage to drop coverage. Those previously covered employees, then, may be Medicaid eligible, and states will become liable for people previously covered in the private market. Although the costs of this phenomenon are unknown, Representative Dunnigan expressed that this situation will certainly arise in some states "if the Secretary establishes a national one-size-fits-all essential benefits package."

Utah's Insurance Exchange

When committee member Dr. Nelson asked Representative Dunnigan for details on how the Utah exchange is working, Representative Dunnigan noted that Utah began by operating a pilot program of the exchange for small employers; the exchange opened to the broader market of small and large employers in January 2011.[11] By February 2011, 62 employer groups were participating (covering about 1,300 lives). Subsequently, additional employer groups joined. Utah opted to phase-in the program, he said, because it allows the state to address issues as they arise.

This discussion of the exchange prompted Dr. Nelson to ask for further details about how the state determined the basic benefit package. Representative Dunnigan said the basic benefit package has been in place for "a number of years." Utah NetCare, which is Utah's "version of an EHB package," was designed to be a third less expensive than the average employer-based premium in the market. While the basic benefit package is currently available and being purchased, "most people purchase benefit packages in excess of the basic requirements."[12]

[11] As of March 30, 2011, the Utah exchange is no longer permitting large employer participation (State of Utah, 2011).

[12] According to Utah's largest commercial insurer with about 50 percent of the market, the enrollment or uptake in the minimum NetCare among their members represents about 0.005 percent of the overall market. Personal communication with James Dunnigan, May 4, 2011.

PRESENTATION BY MR. MATTHEW SALO, THE NATIONAL GOVERNORS ASSOCIATION (NGA)

Mr. Salo, the Director of the Health and Human Services Committee of the NGA concluded the panel by discussing implementation issues related to insurance exchanges. Even before the passage of the ACA, he said, the NGA had convened groups of key state officials (e.g., governors' offices, health officials, Medicaid directors, and insurance commissioners). These conversations, among others, allowed Mr. Salo to confirm statements made by the previous panelists: notwithstanding the passage of the ACA, health insurance "does remain and will remain" largely a state issue. This holds true, he said, "whether you are talking about regulation, or licensure, or coverage mandates, or the state's role as a purchaser of health insurance." By 2014, he claimed, states will be the largest purchaser of health insurance in this country.

State Flexibility

Mr. Salo echoed Representative Dunnigan in saying that because political and cultural factors drive health insurance regulation, benefit mandate decisions, and benefit design, state-by-state decision making is necessary. Mr. Salo argued that "this flexibility will avoid dealing with a national standard that many states cannot meet either because it is too high, or because it is too low." He emphasized that governors need a "highly flexible framework" for determining state-specific benefit packages that "drive innovation" through value-based insurance design (VBID). Conversely, granular federal mandates about types of services and duration of services, he said, will inhibit innovation. Dr. Kingsdale interjected, noting that he disagreed that states should have flexibility in determining the EHB package. The ACA specifies, he said, a national EHB package. Mr. Salo concluded by advising the committee to consider fiscal and political sustainability by ensuring its recommended EHB package is realistic from fiscal and political perspectives.

Question & Answer Session

Committee member Dr. McGlynn asked the panelists to comment on the role of the government in developing a process for "gathering the evidence needed for decision making" given that states are "cash strapped," states may be unable to gather this evidence on their own, and that a federal process may prevent state-by-state inconsistencies in the evidence used. Dr. Cowdry responded that research undertaken by large carriers or "independent institutions that have been set up to do exactly this kind of guideline development and guidance" could prospectively minimize discrepancies in evidence as opposed to addressing discrepancies only through an appeals process. He cautioned, though, that this process would need to be insulated from politics and that Medicare should not "dominate" the process. There is a need for private sector entities, Dr. Cowdry said, "to come to a greater agreement about what is medically indicated."

Representative Dunnigan supported Dr. Cowdry's argument, noting that these determinations need to come from the scientific community, not from policy makers. "If there could be a national standard of evidence-based medicine and favorable outcomes that the states could evaluate and adopt," he said, "it needs to be divorced from policy makers." Dr. Kingsdale added that while Massachusetts analyzes the cost impacts at the state level "as new benefits or proposals crop up," a national database and national analysis would "make a lot of sense."

Committee member Mr. Koller followed up on these responses by asking the panelists for ways in which the EHB process could "assure relative integrity, preserve flexibility but secure some degree of consistency, and reduce the state-to-state variation seen in practice." Dr. Sammis responded that Maryland's MHCC can estimate the cost of its standard benefit plan because the plan has "specificity between the benefits, the limitations, the exclusions, and the cost sharing," rather than having just a list of benefits. It is not possible, she said, "to price out benefits" without considering the cost-sharing requirements. The specification of the EHB would "provide some guidance to the carriers as to what types of criteria they need to be mindful of when they develop policies and procedures for medical management." She cautioned the committee that being too "prescriptive about cost sharing" would impede state decisions about what level of cost each state is "willing to impose upon its own citizens."

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5

Medical Necessity and Use of Evidence

The U.S. Department of Health and Human Services (HHS) asked the committee to assess how insurers determine medical necessity. In this session, Dr. Alan Garber, staff physician at the VA Palo Alto Health Care System and Director of the Center for Health Policy at Stanford University, delineated the differences between the application of medical necessity and the development of a benefit package. He reviewed some precedents related to medical necessity, specifically federal court rulings and a definition developed by a consensus committee convened by Stanford University with its associated criteria including consideration of cost. Additionally, Dr. Barbara Warren, the Director of the Hunter College Institute for LGBT Social Science and Public Policy spoke on behalf of Consumers United for Evidence-Based Healthcare (CUE).[1] She addressed consumer support for the use of evidence in determining essential health benefits (EHB), explored criteria and definitions for medical necessity from the consumer's standpoint, and expressed ways to incorporate consumers in the process for updating the EHB.

PRESENTATION BY DR. ALAN GARBER, VA PALO ALTO HEALTH CARE SYSTEM AND STANFORD UNIVERSITY

Dr. Garber began by clarifying the difference between a coverage decision (i.e., what an insurer covers as a general benefit category) and a medical necessity determination (i.e., what intervention is deemed appropriate for a particular person). A coverage decision is a policy decision based on the general needs of the broad population group insured under a benefit plan; in general, this coverage policy refers to the broad categories of services (e.g., hospitalization) for which the insurer will pay, as well as whether the insurer will pay for a specific intervention (such as a new surgical procedure). A medical necessity determination, on the other hand, determines whether the insurer will pay for an intervention in a very specific instance—for example, when an individual patient requires hospitalization and a specific surgical intervention. To complicate these distinctions, not every treatment that is potentially medically necessary is covered by a plan. Plans usually specify categorical exclusions that are never covered. For instance, some commercial plans categorically exclude maternity care. Conversely, some plans,

[1] The 29 member organizations represent a full range of health and behavioral health issues and concerns from cancer to geriatrics; minority health; addiction recovery; environmental health; lesbian, gay, bisexual, and transgender health; mental health; women's health; disabilities; and other issues. More information can be found on their website: http://us.cochrane.org/consumers-united-evidence-based-healthcare-cue (accessed May 10, 2011).

including Medicaid, may cover certain services that are not considered medical services *per se*, and therefore, would not be medically necessary.

When committee member Dr. Guzick asked Dr. Garber to explain the role of medical necessity in defining the EHB, Dr. Garber replied that "once one gets away from decision making about an individual case, one is no longer speaking about medical necessity; instead, we are speaking about coverage policy." Over the past 15 or 20 years, he said, almost "everything proven effective" has been included in the defined set of benefits. This approach, he argued, ignores the cost implications of covering a particular service, resulting in a "very costly bundle of services." Dr. Garber advised that if value is to be considered in determining what is essential, there should be a discussion about what criteria are used to define value and how those criteria should be applied. Dr. Garber suggested that cost-effectiveness analysis or other tools implemented around the world could be applied.

Court Direction on the Meaning of Medical Necessity

The Second Circuit Court of Appeals has decided numerous cases related to medical necessity and in *Mario v. P & C Food Markets, Inc.*,[2] specifically ruled that in the absence of a medical necessity definition in the plan document, the term medical necessity refers to what is medically necessary for a particular patient and consequently is not a blanket determination of whether coverage is appropriate:

> Unless the contrary is specified, the term "medical necessity" must refer to what is medically necessary *for a particular patient,* and hence entails an individual assessment rather than a general determination of what works in the ordinary case.[2]

Furthermore, a class action lawsuit filed in 2000 and consolidated in the U.S. District Court for the Southern District of Florida resulted in a generally agreed upon definition of medical necessity.[3] Under the terms of the settlement agreements, the defendants (including Aetna, CIGNA, Anthem/WellPoint, Humana, and other insurers, together with state and county medical societies and 900,000 physicians, agreed to accept the following definition:

> "Medically Necessary" or "Medical Necessity" shall mean health care services that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are: (a) in accordance with *generally accepted standards of medical practice*; (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. For these purposes, "generally accepted standards of medical practice" means *standards that are based on credible scientific evidence published in peer-reviewed medical literature* generally recognized by the relevant medical community or otherwise consistent with the standards set forth in policy issues involving clinical judgment. (Kaminiski, 2007)[4]

The definition that emerged from this class action settlement was only required to apply to those insurers participating in the settlement.

In determining medical necessity, one test is whether the intervention meets generally accepted standards of medical practice. Dr. Garber stated that a "sea change has occurred over the decades in what is meant by generally accepted standards of medical practice." In the past, he said, the phrase referred to "any kind of care that a physician deemed necessary and appropriate for a patient." The above definitions, however, state that the generally accepted standards of medical practice have evolved to mean standards that are based on credible scientific evidence. This evolution in terminology corresponds to what Dr. Garber maintained has been an increased reliance in the provider community on the published clinical and scientific literature.

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[2] *Mario v. P & C Food Markets, Inc.,* 313 F. 3d 758 (2nd Cir. 2002).

[3] In re Managed Care Litigation. S.D. Fla. MDL No. 1334. Settlement approved December 31, 2005.

[4] Emphasis by using italic font was added to excerpts from Kaminski, 2007, by Dr. Garber.

Furthermore, Dr. Garber highlighted that the court's agreed upon medical necessity definition explicitly recognizes that relative costs can and should play a role in medical necessity determinations by stating "not more costly than an alternative service or sequence of services." This, he said, is often a controversial aspect of medical decision making.

Stanford Definition of Medical Necessity

Before the above-discussed court decisions, a Stanford University project brought together various stakeholders to generate a model definition of medical necessity intended for use both by private health plans and state Medicaid programs (Singer et al., 1999) (see Appendix C).

After "a great deal of discussion and debate," the definition that emerged from a 1999 workshop achieved what Dr. Garber described as "broad consensus among participants" although not necessarily agreement about each particular provision. The preamble to what is now commonly called "the Stanford definition" broadly states that for an intervention to meet the test of medical necessity and be covered by an insurer, the intervention first had to be included in a category of service not specifically excluded in the benefit contract.

The Stanford definition includes five criteria: who has decision-making authority, the purpose of the intervention, the scope of the intervention, the standards of evidence, and the value (i.e., cost-effectiveness) of the intervention.

Authority means the intervention needs to be recommended by the treating physician and determined appropriate by the plan medical director or his designee. This criterion relates to both Medicaid and private plans.

Purpose means the service in question is a health intervention that is intended to treat a medical condition. The boundaries of what is and is not considered medical care engenders a great deal of debate, such as current controversies about coverage for some treatments for common conditions like autism.[5] Therefore, the purpose criterion, Dr. Garber said, is meant to "set the boundaries more or less for what is the health intervention and what is a medical condition." In this definition, treatment encompasses diagnostics and other aspects of care, and can be thought of as the various interventions used to manage a condition from the physician's point of view.

Scope refers to the appropriate supply or level of service. It considers potential benefits and harms to the patient, such as where the treatment or the intervention might be delivered (inpatient or outpatient, or only in specialized centers of excellence with demonstrated competence in specific types of cases).

Evidence means the intervention is effective, can reasonably be expected to produce the intended results, and that the expected benefits outweigh the potential harms. Dr. Garber noted that "evidence is infrequently cut and dried" and therefore, the following questions need definition: what is meant by evidence, what standard of evidence is appropriate, and what evidence is inadequate? Further, he said, the Stanford definition proposes a distinction between new interventions and existing interventions in assessing evidence for effectiveness. For new interventions, effectiveness is based on scientific evidence consisting of various kinds of data of varying degrees of rigor, including randomized controlled trials and properly designed observational studies. For existing interventions, effectiveness is determined first by scientific evidence, then by professional standards and expert opinion. This distinction reflects the practical difficulty of applying high standards of evidence to treatments that clinicians have long accepted as effective. If scientific evidence is unavailable, then professional standards of care are acceptable. And if professional standards of care do not exist or are contradictory, then expert opinion may be relied on to make decisions.

Value explicitly refers to the cost-effectiveness of the intervention compared to alternative interventions, including no intervention. An intervention is deemed cost-effective if the benefits relative to the costs represent an efficient use of resources for patients. Dr. Garber stated that cost-effectiveness has been "an area of contentiousness in both private and public insurance, but more openness to considering value has been developing over time."

[5] Parents seeking care for their children with autism wish to explore all potentially helpful treatments. To ensure affordability and prevent adverse selection for dependent coverage, insurers have traditionally distinguished between non-medical benefits (e.g., education) and medical benefits.

Cost Considerations in Insurers' Decision Making

Reiterating a point made by Dr. Jonathan Gruber (see Chapter 4), Dr. Garber noted that "the more expansive your definition of medical necessity, the greater the cost of a benefit package." That is not a surprise, Dr. Garber said, but "what may be a surprise is how small changes in expansiveness can give rise to very large changes in cost."

When committee member Dr. Ho asked about the differences between the settlement language and Stanford definition of medical necessity with respect to cost considerations, Dr. Garber noted that the settlement came after the completion of the Stanford project, and that while he did not have a "head-to-head comparison" to utilize, there are some differences in the way that cost is considered. The settlement language confines medically necessary treatments to those that are "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." The Stanford definition, by comparison, applies a cost-effectiveness criterion, which assigns a much greater role to cost considerations.

The aforementioned court settlement definition of medical necessity was agreed upon by providers and large health insurers, all of whom agreed on cost consideration as a valid parameter. An earlier anonymous survey of insurers conducted in 2000 and 2001 by the Stanford Center for Health Policy (and before the settlement agreement), looked at the use of cost in plan decision making. At the time of the survey, only 40 percent of plans conducted formal cost-effectiveness analysis, and about half selectively applied cost considerations in pre-authorizations for some interventions. Fifty-four percent of surveyed plans had explicit coverage policies that included some notion of cost, and 58 percent required the use of less costly interventions before more costly ones (e.g., a generic pharmaceutical product before a branded drug) (Garber, 2004).

The same survey examined how plans evaluated costs when considering whether to cover a new health intervention. If the new intervention would be equally effective for the same costs as existing interventions, almost all plans (94 percent) said that they would cover the intervention. If the intervention was equally effective but cost more, the majority (84 percent) would not cover it. If it was less effective for the same cost, only three percent of plans said they would cover the intervention, and eight percent would cover less effective interventions for less costs (Garber, 2004). In sum, Dr. Garber said, a plan tended not to cover new interventions that were less effective, even if the intervention was substantially less costly. If the new intervention was more effective than interventions already available, plans were likely to cover it regardless of cost. The survey suggests that for plans, "effectiveness trumps costs."

Conversely, Medicare does not consider whether a new intervention would result in equivalent or lower total costs for the program. In the 1990s, Medicare attempted to make cost a component of its coverage decision making process. The Health Care Financing Administration (HCFA) (Centers for Medicare & Medicaid Services' [CMS'] predecessor agency) indicated in a draft rule that it would cover a service depending on four categories, including cost. The cost category assessed "whether the item or service resulted in equivalent or lower total costs for the Medicare population than the currently covered alternative." After extensive public outcry during the public comment period, the proposed rule was withdrawn (HCFA, 2000). Subsequently, CMS has been reluctant to explicitly consider cost when making coverage decisions.

Fair Processes

When committee member Dr. James Sabin asked for possible meanings of "fair process" in the context of the EHB program, Dr. Garber replied that fair processes could apply to both benefit coverage and medical necessity decisions. There are precedents, Dr. Garber said, for incorporating public deliberations into benefit coverage decision making. He cited the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) as "a good example of a very public process with a great deal of opportunity for public input."

While individual medical necessity cases cannot be subject to a public process as they involve individual patients and confidential information, there can be, Dr. Garber pointed out, a public process for "vetting the rules that are used to make medical necessity decisions" and establishing an appropriate appeal process. This exchange prompted committee member Mr. Koller to ask what standards for transparency could increase consumer confi-

dence in the medical necessity decision-making process. Dr. Garber stated that consumers could best participate in the benefit design process if they were better trained to effectively represent the public. Other countries, he said, have embedded consumers in the benefit design processes (Sabik and Lie, 2008). While these consumers are not experts on health care or these kinds of decision-making processes, they receive training to prepare them to examine the intervention under consideration and understand complex statistical arguments. After a week of training, Dr. Garber said, the consumers can participate "at a much higher level and give more meaningful input."

Medical Necessity Determination in the Future

Dr. Garber stated that numerous reforms introduced in the Patient Protection and Affordable Care Act (ACA) raise the question of whether medical necessity determinations will continue to be an important issue as the law's provisions go into effect. For example, he said, if payment changes put more financial risk on the shoulders of providers, then providers "will have more of a stake in ensuring that only effective care and necessary care is delivered, so medical necessity decision making may turn out to play a lesser role." The nation is, however, "years off from the time when medical necessity decisions will be unnecessary or much less prominent in determining which care is delivered."

Dr. Garber concluded by noting that one of the greatest challenges for coverage policy and medical necessity decision making is how to account for individual variation in ability to benefit from an intervention. "If there is an Achilles heel in our reliance on evidence," he said, "it is that we tend to have much better evidence about averages for populations than we have about how subgroups might derive greater or lesser benefits from any intervention. The process has to be flexible enough to accommodate that."

PRESENTATION BY DR. BARBARA WARREN, CONSUMERS UNITED FOR EVIDENCE-BASED HEALTHCARE (CUE)

Dr. Warren, who spoke on behalf of the CUE, began by describing the organization. CUE is a national coalition of health and consumer advocacy organizations established in 2003 in response to an invitation from the U.S. Cochrane Center to create a partnership between consumer advocates and scientists. The aim of the partnership is to improve consumers' ability to engage in and demand high quality health care by providing tools that educate constituents about evidence-based health care and the use of evidence in health care decision making. The aim, Dr. Warren stated, is to get consumers "engaged in a much more proactive way."

CUE members, Dr. Warren said, advocate for the development of a "consistent, universal definition of medical necessity that emphasizes quality and clinical effectiveness above cost and resource utilization." She stressed the importance of transparency in the medical necessity decision-making process, particularly as it relates to who gets to make the final determination on what interventions are medically necessary, and what the appeals process will be in the event that the patient or provider who is appealing does not concur with the decision.

Dr. Warren noted that although the Stanford definition may be a viable and useful model, it is not a definition with which most consumers and consumer advocates are familiar. Therefore, any definition needs to be widely disseminated with a process for review, discussion, and revision.

Consumer Support for Evidence-Based Medicine (EBM)

Consumers, Dr. Warren acknowledged, are often represented as opposed to limits or even to discussing what care might be essential and necessary. But without an understanding of the purpose of such terminology and without being invited to engage in the discussion of what it means, the determination of EHB is "scary because it sounds like something might be limited or denied to anyone in need." Therefore, Dr. Warren argued, inclusion and education are critical issues for consumers. By including consumer advocacy organizations and coalitions in EHB decisions, consumers can be engaged in the process.

CUE, for instance, trains consumers as effective partners in the development and implementation of systematic reviews, clinical trials, other research studies, and clinical guidelines panels. The coalition also translates evidence

into widely disseminated "plain language summaries" that are more easily understood and used by laypersons. Consumer constituents actively seek out this information and use it to more readily engage in discussions with providers about the benefits and harms of treatment.

Research, including Cochrane systematic reviews, shows that enhanced patient-provider communication and shared decision making may increase patient adherence to treatment, improve outcomes, and reduce the need for more invasive and costly treatments (Naik et al., 2008; O'Connor et al., 2003). Educated consumers, Dr. Warren argued, are more cost-effective. The first and central principle espoused by CUE is that policy makers, providers, and insurers need to commit not only to integrating the best evidence available into benefit decisions, but also to including consumers in these benefit decision processes. The second principle recommended by Dr. Warren on behalf of the CUE is that benefit decisions recognize diversity. The EHB package, she argued, should offer a "reasonable range of choices" that recognize that each consumer is an individual. "One size," she said, "cannot fit all."

Expanding the Definition of Best Evidence

In defining what constitutes the "best available evidence," CUE urges that reviews of the evidence take into account clinical expertise, patient values and needs, standards of care, and clinical practice guidelines developed through a combination of research, clinical expertise, and consumer input. For some populations, Dr. Warren said, this broader definition of evidence makes a critical difference in being able to access needed medical care. For instance, although there are well-established clinical guidelines on the necessity for and appropriate administration of hormone replacement therapy for transgender patients, the lack of clinical trials and systematic reviews supporting such treatment remains a barrier for many transgender patients in accessing coverage for treatment. Additionally, while clinical trials may establish research-based evidence, for example in pharmacological treatment, they do not always adequately involve diverse racial and ethnic populations, women, children, or adolescents. Furthermore, Dr. Warren argued, "efficacy in a controlled clinical setting may not prove to be effective in the real world where patients have intervening health and environmental factors that may impact their treatment outcomes."

Consumer Engagement in Updating Covered Benefits

"Nothing About Us Without Us!" is often cited by members of the disability movement. Dr. Warren explained that this slogan means that policies should not be defined without the full and direct participation of groups affected by that policy. These groups, she said, must involve national, ethnic, ability-based, or other groups that are often marginalized from political, social, and economic opportunities. CUE promotes full consumer inclusion in the development and implementation of policies and guidelines that determine access to care. Investing in building consumer capacity for effective participation, she argued, pays off in that consumers can be invaluable members of an interdisciplinary team by providing insights and perspectives that are often not apparent to clinicians, policy makers, and industry representatives.

CUE suggests that the process for updating the EHB includes the necessary infrastructure to engage consumers in an equitable way. A national subscription to the Cochrane Library, for instance, would enable all consumers to access the wealth of systematic reviews on the effects of interventions for prevention, treatment, and rehabilitation. Cochrane resources are currently limited to government entities, hospitals, and universities that can afford paid subscriptions. Furthermore, Dr. Warren noted, providers, policy makers, and industry representatives participating in these processes are often financially supported or compensated for their participation. Travel support and stipends for consumer participation would enable more consumers and consumer advocates to engage in an inclusive and equitable way.

Dr. Warren concluded by reiterating that full disclosure, complete transparency, and consumer education will allow the committee and HHS to engage consumers in understanding medical necessity and what is meant by essential health benefits. She also noted that consumers need sufficient information to understand the benefit choices available. A "middle ground approach" has proven helpful in Medicare supplemental policies, and is now being implemented in Medicare Part D with the aim of reducing the confusion created by having too many drug

benefit designs. Reasonable and informed choice affords consumers and providers the ability to select and then implement the package that is the "best fit for that consumer's needs and condition."

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6

Insurer Decisions of Benefit Coverage and Medical Necessity

The Institute of Medicine (IOM) committee is tasked with considering how both public and private insurers choose benefits, develop clinical policies, and make medical necessity determinations. Dr. Louis Jacques began the panel discussion by providing lessons gleaned from Medicare's process for deciding what is covered. Dr. Jeffrey Kang then described how CIGNA develops a benefit plan and how the benefits offered by a typical CIGNA employer plan compare to the categories of care listed in Section 1302 in the Patient Protection and Affordable Care Act (ACA). He then proposed an approach to developing essential health benefits (EHB). Dr. Virginia Calega, speaking on behalf of the Blue Cross and Blue Shield Association (BCBSA), expanded on the factors insurers take into account in choosing covered benefits and promoting evidence-based practices. Dr. Robert McDonough addressed Aetna's process for evaluating medical technologies and defining clinical policies. Ms. Carmella Bocchino of America's Health Insurance Plans (AHIP) concluded the panel by emphasizing the need to balance the scope of benefits with the affordability of premiums and to offer consumer choice among a variety of health plan options.

PRESENTATION BY DR. LOUIS JACQUES, CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS)

Dr. Jacques, director of the Coverage & Analysis Group at CMS, called the task of determining the scope of the EHB "extraordinarily cumbersome," and advised the committee that it will "be beat on by everybody." Presuming public health is important in designing the EHB package, he said, the committee's high-level priorities "aren't going to be remarkably different from" the priorities used by federal agencies or private plans. To assist the committee in its process, he began by providing a set of considerations that Medicare uses when designing its benefit plan:

Evidence-based care. Current incentives in the health care system—whether related to physician, patient, hospital, or manufacturer behavior—are not necessarily aligned with evidence-based practice, Dr. Jacques said. To what extent will science matter? How much evidence do you need? What kind of evidence is needed? Dr. Jacques advised the committee that whatever it decides regarding these questions, "it is better to be forthright, upfront, with whatever you design."

Innovation. Do you want to incent medical technology innovation and support beneficiary participation in clinical trials? The realities of insurance mean that plans "pay for whatever physicians and other providers

choose to submit bills for." This is very different, Dr. Jacques said, from prioritizing health care technologies that are of the most public benefit.

Precedents. Do you want to rely on the rulings or regulations of federal agencies as benchmarks for EHB coverage policy? The committee could, for instance, say that EHB are directly tied to U.S. Food and Drug Administration (FDA) approval, or the withdrawal of FDA approval, of a particular drug. He cautioned the committee, though, to consider that because the Department of Defense (DOD) TRICARE, U.S. Deparment of Veterans Affairs (VA), and Medicare serve special populations (DOD, 2011; VA, 2011), specific covered benefits under their benefit plans may not necessarily align with the needs of the population insured under an EHB package.

Reactivity vs. pro-activity. Will your coverage policies be used for medical review or audit? The committee's definition of medical necessity, he noted, will impact the ability of individuals to appeal for "individual consideration" of a specific benefit.

Administrative agility vs. formalized consistency. Developing policies that try to anticipate every eventuality may not be feasible, he said. Rather, the system might need to naturally evolve. The committee will need to consider, he said, whether the U.S. Department of Health and Human Services (HHS) wants "pre-written policies established to enhance transparency" or if it wants the capacity to provide individual consideration for coverage decisions. Whatever decisions are made will require balance among different features as outlined in the grid across the four dimensions of being reactive versus proactive and having formalized consistency versus administrative agility (see Figure 6-1).

Dr. Jacques implored the IOM and ultimately HHS to "design a system that keeps in mind a more long-term view." All of the early decisions will be precedents for what happens later, he said. Therefore, decisions about EHB

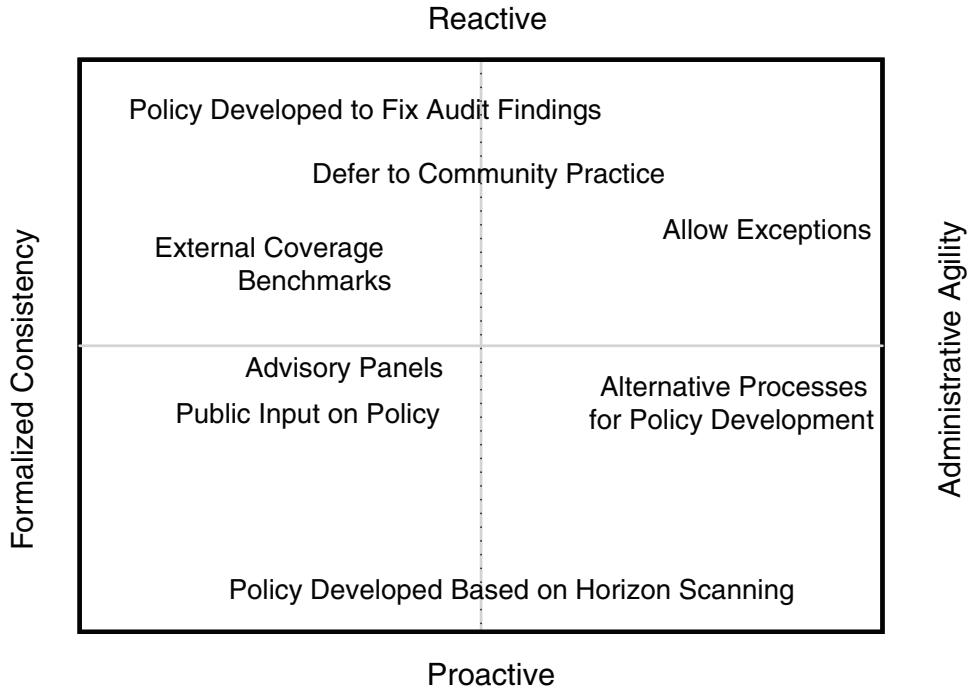

FIGURE 6-1 Defining benefit plans requires balancing administrative agility or consistency with the need to proactively or reactively define benefits.
SOURCE: Jacques, 2011.

"must be built on integrity, credibility, and consistency." While stakeholder groups are influential, he cautioned the committee that they all have their "own particular interests at heart" and that there is a tension between engaging these stakeholders and "abdicating responsibility" to them. It is important, he said, to build common ground around agreed upon principles.

When prompted by committee chair Dr. Ball to explain how CMS accounts for cost in its coverage decisions, Dr. Jacques noted that the standard response of CMS officials is that "Medicare does not consider cost in actually making these decisions." And this remains true, he said. *Hays v. Sebelius*,[1] for instance, overruled attempts by Medicare or its contractors to implement least costly alternative policies. In *Hays*, the court ruled that CMS could not reduce the payment amount, even for identical drugs that were packaged differently.

PRESENTATION BY DR. JEFFREY KANG, CIGNA CORPORATION

Dr. Kang, the chief medical officer for CIGNA Corporation discussed how CIGNA "constructs" a benefit plan, how covered benefits interact with medical necessity, and which issues the committee might consider as it debates what is "essential" and what defines a "typical" employer.

Inclusions and Exclusions in Benefit Coverage

Benefit design is a contractual agreement between a plan and a customer that identifies excluded and included services; in the case of included services, each service may be subject to a medical necessity determination to assess appropriateness for an individual patient. The purpose of the medical necessity determination, Dr. Kang said, is not cost, but rather, "to ensure that the services delivered are reasonable, necessary, safe, and effective." The contractually outlined excluded services may be ruled out regardless of medical need and the availability of a strong supporting scientific evidence base of effectiveness of treatment. An oft-cited example of an exclusion is that Medicare fee-for-service did not cover oral prescription drugs until Medicare Part D was implemented in 2006. This was not because prescription drugs were not medically necessary. Rather, Medicare made a policy decision based on affordability.

The distinction between included and excluded services has implications, Dr. Kang said, for determining the EHB. Employers can purchase buy-ups or riders if they wish to include "typically excluded services." In the exchanges, individuals or employers could purchase supplemental policies to meet individual lifestyle needs. For example, acupuncture, cosmetic surgery, dental and vision care, infertility care, and experimental or investigational treatments are often excluded services, but could be added through individually purchased riders.

Typically, Dr. Kang said, plan documents also reference cost sharing arrangements (deductibles, co-pays, co-insurance) for each benefit category, and included items might have limits for specific services (e.g., physical therapy might be covered for up to 30 visits per year). Dr. Kang noted that sometimes, certain services are not explicitly included or excluded in the plan document. If a requested service can be reasonably construed to fall within an included benefit category, then coverage determination is based on medical necessity. For example, kidney dialysis is an example of a service that may not be explicitly listed as a covered service within the plan document but falls within a general benefit category, so it is covered if medically necessary.

Benefit limits, Dr. Kang emphasized, are not just "arbitrary numbers"; the limits are based on the plan's evaluation of population needs. When an employer requests a rehabilitation benefit, for example, CIGNA uses its data to determine the appropriate number of physical therapy visits that are adequate for a restorative benefit. As 90 percent of enrollees "accomplished their restoration" within 30 visits, the number of physical therapy visits is set at 30. If an employer wants a broader benefit that includes maintenance or improvement of function over a person's baseline, CIGNA works with the employers to price the benefit accordingly.

In response to a query from committee member Dr. Santa, Dr. Kang suggested that denials based on medical necessity are rare within CIGNA. Last year, he said, CIGNA paid for 91 million claims in the United States and approximately 99 percent of those were paid without a denial or required pre-authorization. Approximately .006 percent of total eligible claims were not ultimately approved. Of the initial denials (7,974 cases), 32 percent

[1] *Hays v. Sebelius,* Case number 08-5508, DC Circuit Court of Appeals.

TABLE 6-1 Scope of Included Benefits: ACA vs. CIGNA's Standard Employer Plan

Item or Service	Included in ACA—Section 1302(b)(1)	CIGNA Standard Medical Plan
Ambulatory Patient Services	Included	Included
Emergency Services	Included	Included
Hospitalizations	Included	Included
Maternity and Newborn Care	Included	Included
Mental Health and Substance Use Disorder Services, including behavioral health treatment	Included	Included
Prescription Drugs	Included	Included
Rehabilitative Services and Devices	Included	Included
And Habilitative Services and Devices	Included	Excluded
Laboratory Services	Included	Included
Preventive Services	Included	Included
And Wellness Services (Needs Definition)	Included	Buy-Up (separate programs)
And Chronic Disease Management	Included	Included
Pediatric Services (Medical)	Included	Included
Pediatric Services (Oral and Vision Care)	Included	Buy-Up (separate coverage)

SOURCE: Kang, 2011.

were overturned mostly because of new or additional clinical information made available upon appeal. Less than 0.1 percent were initially denied and after the appeals process was exhausted, about .006 percent of total claims were completely denied.[2]

Comparing a Standard Employer Plan to ACA Categories of Care

Dr. Kang compared the 10 categories of care listed in Section 1302 of ACA with the CIGNA Standard Medical Plan; to facilitate comparison, he disaggregated the 10 categories into 14 more discrete categories (Table 6-1). Typically, he said, large group (50 or more employees) medical policies exclude habilitative services and devices, without options for buy-up. Pediatric oral and vision care, and what he called the ambiguously defined "wellness services" (perhaps, smoking cessation, weight management programs) are typically excluded from the standard plan but available as buy-ups and purchased as separate products. Dr. Kang noted that the committee will have to "sort through" the conflict between the 10 categories of care required by the ACA and the requirement that the EHB package is similar to a typical employer plan. Approximately 99 percent of CIGNA's medical coverage business is in the large group market, which Dr. Kang defined as 50 employees or greater. If the benchmark for "typical" is more precisely defined as large employer group plans, the benefits offered under these plans would be "fairly comprehensive and not terribly far apart from the categories" included in Section 1302.

A Proposed Framework for a Tiered Benefit Design

Dr. Kang suggested that the committee consider a theoretical framework that adds more benefits at each actuarial tier.[3] For each category of care, Dr. Kang proposed placing services on a continuum from the most essential services (e.g., life preserving services such as hospitalization to treat a heart attack) at the bronze level to services that may be life-enhancing but not essential (e.g., treatment for varicose veins, infertility, prescriptions for Viagra) at the platinum level. Most carriers would put preventive services, for instance, on the life preserving side of the continuum and offer "first dollar coverage" for these preventive services. The middle of the continuum would be

[2] Personal communication with Jeffrey Kang, CIGNA Corporation, February 17, 2011.

[3] Section 1302(d)(1)(A)-(D) outlines different levels of coverage that are actuarially differentiated: bronze is actuarially equivalent to 60 percent of the full actuarial value; silver 70 percent, gold 80 percent, platinum 90 percent.

comprised of chronic care management services, among others. For example, a healthy 20-year-old might define the EHB as life-preserving services that offer protection from catastrophic events,[4] and would therefore prefer a bronze plan with a high deductible, a limited scope of services, and a lower premium. A chronically ill, disabled individual may, on the other hand, define the EHB as those that span the continuum from life-preserving to life-enhancing; this person, Dr. Kang said, might be willing to pay a higher premium. If each tier has to include the exact same scope of services, individuals would make decisions based solely on the tradeoff between the amount of cost sharing and the premium. For this reason, Dr. Kang argued in favor of including differing scopes for differing tiers.[5]

The reason, he said, for additional refinement is that the definition of what constitutes essential care currently "depends on the eye of the beholder." Committee member Ms. Ginsburg asked Dr. Kang who should make the determination of where a particular service is placed on the continuum. This framework, he said, was not based on scientific analyses, but rather, is an illustrative concept based on multiple conversations with clients (employers) and customers (individuals) on what services might be considered essential. When Ms. Ginsburg also noted that including a differential scope of services in the tiered plans could segment the market and "destroy the risk pool," and did not seem permissible under ACA, Dr. Kang responded that some employers are beginning to offer tiered plans with different premium contributions, and insurers usually offer high/low options. Furthermore, in the individual market, individuals will already self-segment; you are unlikely to find many young people, he said, who will buy the platinum plan. Dr. Kang cautioned the committee to keep in mind that interpretation of the term *essential* in the individual market is going to vary based on an individual's circumstances.

Dr. Santa asked whether CIGNA's current plans offer any benefit categories beyond those listed in Section 1302. Dr. Kang stated that the services included in Section 1302 are open to interpretation but that for larger groups serving more than 50 employees, services that might not be included in the ACA categories include (1) home care—while it could be considered under ambulatory care services, in CIGNA's benefit language, it is a separate category; (2) skilled nursing facility care—while it could be considered under rehabilitation service, in CIGNA's benefit language, it is a separate category; and (3) hospice is also a separate category.

Given Dr. Kang's previous role working for CMS, Dr. Ball asked Dr. Kang to contrast the coverage policy decision making within CMS and CIGNA. Dr. Kang replied that there is actually "very little difference" in how coverage policy is determined, but that there are differences in how the policies get implemented. On the commercial side, for instance, insurers will use prior authorization, but this does not "exist" in Medicare fee-for-service; instead, Medicare uses a post-payment approach for review of appropriateness. Another difference is that because Medicare has a scope of benefits that are legislated, the issue, Dr. Kang said, becomes what services are "reasonable and necessary." Neither CIGNA nor Medicare uses cost as part of the decision-making process for medical necessity; these determinations, he said, are strictly based on evidence and whether the services have been proven safe and effective. The enforcement of these policies, though, "is completely different."

PRESENTATION BY DR. VIRGINIA CALEGA, BLUE CROSS AND BLUE SHIELD ASSOCIATION (BCBSA)

Dr. Calega, the Vice President for Medical Management and Policy at Highmark Blue Cross Blue Shield (Highmark), spoke on behalf of the BCBSA. She began by noting that the definition of EHB will "primarily impact individual consumers, small businesses, and the self-employed," as these are the individuals who are most likely to purchase insurance through the exchanges. Highmark and BCBSA, she said, recommend that the definition of EHB "preserve an insurers' ability to utilize medical management tools, including medical necessity evaluation." She advocated for the initial scope of the EHB package to reflect a small business' typical plan; extensive research has shown that the individual and small group markets are especially sensitive to price as individuals in such plans bear much of the premium costs (Feldman et al., 1997; Gruber and Lettau, 2004; Hadley and Reschovsky, 2002).

[4] There is an option in Section 1302(e) for a catastrophic plan for people under 30 years of age and for those over the age of 30 if they cannot find affordable coverage in the exchange.

[5] The law specifies, however, that the essential health benefits must be offered at each metal level, and insurers may offer additional benefits.

For example, research on demand for individual health insurance in California found that consumers were sensitive to price and that this sensitivity is generally higher for younger and lower income individuals (Marquis et al., 2004). Benefit design, Dr. Calega noted, influences and is influenced by the size of the premium. Consequently, Dr. Calega cautioned that the committee should keep in mind that an overly inclusive definition of EHB and one that does not require a sound evidence base could negatively impact affordability for consumers and small employers.

Industry Practices for Benefit Design

Benefit design needs to be "an iterative process" that includes input from various sources to ensure meaningful coverage is available at a variety of price points and that premiums match market demand across multiple market segments. If insurers do not offer a plan and a benefit structure at a price that consumers want, "consumers are not going to pick what is offered," she said. Highmark, she said, uses focus groups and satisfaction surveys to ensure it knows what consumers want. Insurance brokers and sales representatives also provide critical information on market demand. Highmark and other BCBSA plans have "very strong ties with their communities" as part of their social mission, and to build credibility, they make their policies and decisions transparent and regularly partner with the employers they insure.

In addition to collecting consumer insights, Dr. Calega noted that Highmark partners with health care providers in the development of medical policies to reflect the standards of care. Furthermore, medical management staff keeps abreast of the medical literature to identify new treatments or changes in medical protocols that may necessitate a change in benefits. Plans also conduct internal performance reviews of their plan portfolios; these reviews consider sales data, medical trends by geographic areas, product types, and benefit designs to ensure meaningful coverage at a variety of price points across different markets.

Using Plan Policies to Encourage Evidence-Based Decisions

Dr. Calega observed that plans have clinical policies in place to help guide medical necessity determinations. The goal of these determinations, she said, is to ensure that the patient receives the most appropriate care at the right time in the right setting. As evidenced by the Dartmouth Atlas,[6] there is a wide degree of variation in the delivery of care; adherence to evidence-based medicine, she said, will help reduce unnecessary variation and inappropriate care. For example, upon discovering a 25 to 35 percent annual increase in utilization of advanced imaging tests (including variations in prescribing and duplicative tests with the potential exposure of patients to unnecessary radiation), Highmark established an advanced imaging program to better manage the appropriate utilization of these tests. First, a privileging program required providers to meet quality and safety standards in addition to being accredited and licensed. Next, a prior authorization program was implemented with the aim of reducing duplicate tests and enhancing adherence to safety standards (Highmark Blue Cross Blue Shield, 2011). Furthermore, Highmark uses clinical decision-support products (e.g., InterQual®)[7] in conjunction with its medical policies; these evidence-based tools guide patients and providers to appropriate treatments.

Committee member Dr. Selby commented that while the "primacy of rigorous evidence is something everyone agrees on," for some medical care, scientifically validated evidence does not exist. In Dr. Alan Garber's presentation (see Chapter 5), for instance, Dr. Garber highlighted that the Stanford definition of medical necessity recognized a need for varying levels of evidence for existing vs. new technologies. Dr. Calega acknowledged there are often gaps in available evidence but reiterated that Highmark uses the best available evidence. In the absence of this evidence, "we work with the published clinical literature that we have," but it is "very difficult" to remove coverage unless the evidence clearly indicates a service is no longer of value. In the case of bone marrow transplant for stage 4 breast cancer, it took 10 years, she said, for evidence to prove it was not of value. Once this evidence was

[6] The Dartmouth Institute for Health Policy and Clinical Practice. 2011. The *Dartmouth Atlas of Health Care.* http://www.dartmouthatlas.org/ (accessed February 9, 2011).

[7] Dr. Calega reports that InterQual® clinical decision support products from McKesson are used by many private insurers, CMS, and military health systems.

available, insurers "pulled back" coverage. "It is critically important," she said, that the nation devote funding to develop more evidence (e.g., through evidence-based practice centers).

Utilization Management Tools

Dr. Calega observed that Congress explicitly preserved the right of group health plans to employ commonly used management techniques like medical necessity.[8] BCBSA and Highmark recommend, she said, that the IOM and HHS do not limit the use of medical necessity or other commonly used medical management tools as part of the administration of EHB. The key reasons for the use of these tools by employers and insurers, including the Federal Employees Health Benefits Program (FEHBP) and Medicare, are to keep coverage affordable while ensuring consumers receive the right care. Medical necessity determination, she emphasized, is a tool that is used after a benefit package is designed.

Dr. Calega gave examples of other utilization management tools that, in addition to medical necessity, should continue to be permissible: (1) coverage of benefits only through licensed providers and facilities within the scope of their license or certification; (2) use of provider networks and cost sharing to direct consumers to those providers that deliver the best value and quality; (3) precertification and prior approval for inpatient hospital admissions except in cases of a medical emergency; (4) precertification for certain outpatient surgeries such as bariatric surgery; and (5) general exclusions for services not medically necessary or appropriate under accepted standards of insurance for medical practice such as for cosmetic services or custodial care.

PRESENTATION BY DR. ROBERT MCDONOUGH, AETNA

Dr. McDonough, the Head of Clinical Policy Research and Development at Aetna addressed the development of clinical policies and patients' rights to appeal medical necessity determinations. He began by noting that while Aetna had once been unique in making its clinical policies publicly available, most other insurance companies are now doing the same.

Clinical Policy Development Process

Aetna's clinical policy unit evaluates technologies to determine whether they are experimental and what the medically necessary indications are for the technology. These evaluations and the policies that they influence are publicly available on Aetna's website.[9] The goal of the policies, Dr. McDonough said, is to "develop objective, clinically supported, and defensible determinations."

Dr. Selby observed that the insurance industry receives considerable criticism and asked how insurers might strengthen their reputation for integrity and credibility; literature and experience suggest that one factor is transparency about processes. Dr. McDonough responded that Aetna has received recognition because of its transparent clinical policies. In the late 1990s, for instance, it was the first commercial insurer to make its policies publicly available on the Internet. Furthermore, legitimacy, he said, can be derived from having outside experts review insurers' policies for reasonableness.

Criteria and Process for Evaluating Technologies

There are a lot of contextual considerations, Dr. McDonough said, in evaluating a technology, including whether the technology relates to a rare condition, whether it is a last resort treatment, or whether there are other established treatments for the condition. If the technology is of minimal cost, there may not even be an evaluation. The "vast majority of technologies," Dr. McDonough said, is not selected for evaluation and is not subject to

[8] Patient Protection and Affordable Care Act of 2010 as amended. Public Law 111-148 § 1563(d)(1), 111th Cong., 2d sess.

[9] *Aetna clinical policy bulletins.* http://www.aetna.com/healthcare-professionals/policies-guidelines/cpb_alpha.html (accessed February 9, 2011).

BOX 6-1
The Blue Cross and Blue Shield Association's Technology Evaluation Center Clinical Coverage Criteria

The following criteria are considered in evaluating a medical technology:

- The technology must have final approval from the appropriate governmental regulatory bodies [when required]
- The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes
- The technology must improve net health outcome
- The technology must be as beneficial as any established alternatives
- The improvement must be attainable outside the investigational settings

SOURCE: BCBSA, 2011.

utilization management (e.g., pre-authorization, limits on visits). His team selects technologies for review based on quantity of use and importance of questions that have arisen regarding the specific technology; the potential impact of the technology on Aetna and its members; the availability of evidence in the peer-reviewed literature, guidelines and consensus statements; changes in regulatory status; or other information that is material to the status of the medical technology.

To evaluate the technology, Aetna has a process in which it looks at evidence in the peer-reviewed literature, the regulatory status, and any relevant clinical practice guidelines and technology assessments. Aetna's clinical coverage criteria are derived from those of the Blue Cross and Blue Shield Association's Technology Evaluation Center (Box 6-1). In addition to these criteria, Aetna considers indications in major drug compendia recognized by CMS, the approval status of technologies from relevant government regulatory bodies (e.g., CMS or FDA), and technology assessments from other reliable sources of information such as the California Technology Assessment Forum and the Blue Cross and Blue Shield Association's Technology Evaluation Center. These assessments, among others, are indexed by Health Technology Assessment International (HTAi).

Each clinical policy bulletin goes through a review and approval process that involves physician advisors, Aetna medical policy and legal departments, and the chief medical officer, who is ultimately responsible for signing off on any of these policies. All policies are reviewed for updating at least annually. Aetna posts its review schedule on the Internet so that the public can comment. Furthermore, Aetna solicits provider input through quality advisory committees, a specialty society liaison group, and a physician advisory group mailbox. Aetna reviews all of the external input to see if patterns might indicate a need to change its policies. After updating, the implementation phase ensures coding practices are aligned; that claims systems are updated to indicate what is covered, not covered, or conditionally covered; and that providers are notified of material changes.[10]

[10] Aetna has agreed to provide 90-day prior notification to its participating providers of all policy changes that will have a material adverse impact on providers. In addition, some states have requirements for prior notification to providers of certain policy changes. These requirements vary from state to state. Personal communication with Robert McDonough, Aetna, May 10, 2011.

Appeals Process

If an individual disagrees with a coverage determination, the member has access to internal and external appeal and grievance procedures. Dr. McDonough noted that all clinical denials include information about how to file an appeal. All medical necessity, experimental, and cosmetic appeals are reviewed by clinicians, with adverse determinations being reviewed by the medical director. Aetna's appeals and grievances processes, Dr. McDonough noted, have to comply with U.S. Department of Labor (DOL) regulations (DOL, 2011), National Committee for Quality Assurance (NCQA) standards (NCQA, 2011), and now, an ACA requirement that members have access to an independent external review after exhausting the internal appeals process.

PRESENTATION BY MS. CARMELLA BOCCHINO, AMERICA'S HEALTH INSURANCE PLANS (AHIP)

Ms. Bocchino, Executive Vice President of Clinical Affairs and Strategic Planning at AHIP, began by building on the comments of the previous panelists and explaining that in a commercial market, employers and plans work together to determine which benefits will be offered. While the categories of services listed in the ACA are similar to the care offered by large employer plans (as described by Dr. Kang and shown in Table 6-1), the ACA expanded benefits to include categories that some consumers have purposely decided to forego in the past. In the small group and individual market, for instance, plans are available that do not offer maternity benefits, prescription drugs, or mental health coverage. Consumers, Ms. Bocchino said, "choose to buy products without those services because: a) they do not feel the services meet their individual needs, and b) it helps to keep the premium down." The ACA has added categories to a minimum standard benefit package and this "appears to be inconsistent with the statement" that the ACA would allow people to "keep the health insurance that they currently have."

Dr. Selby noted that Representative James Dunnigan testified that most enrollees in Utah opt for something more rich than the minimum benefit plan and suggested that a "too basic" minimum benefit plan or a tiered benefit structure might be particularly disadvantageous to low-income and sick people (see Chapter 4). Ms. Bocchino responded that in the commercial market, plans offer a "range of products with different categories of care and different limitations on those services," and individuals decide, on an annual basis, the best fit for them.

Ms. Bocchino advised the committee to "be cognizant" of the fact that "the imposition of richer benefit packages will have the effect of raising group employers' premiums." She emphasized that the "coupling" of the elimination of lifetime benefits and the inclusion of out-of-pocket maximums indicates "congressional intent was to ensure an adequate level of coverage, that consumers have a range of choices, and that these products are affordable."

Medical Necessity

Medical necessity reviews, Ms. Bocchino pointed out, are not conducted on most routine services. These reviews "come into play" if questions arise regarding a lack of evidence for such treatment, its clinical effectiveness or potential for harm, or if the patient did not meet the subpopulation characteristics for which such an intervention might be prescribed. In response to an inquiry from the committee about the degree to which different definitions of medical necessity result in differences in coverage, Ms. Bocchino briefly referenced a Connecticut court settlement that defined a medical necessity determination framework (see Chapter 5 for further discussion of medical necessity) (Kaminski, 2007). This framework, she said, is used throughout the industry. Furthermore, medical necessity is subject to oversight from state regulators and employers; and, in the case of the plans participating in the FEHBP, the U.S. Office of Personnel Management (OPM) reviews and approves the medical necessity provisions used by plans. Dr. Calega supported Ms. Bocchino by noting that Congress did not call for a definition of medical necessity in the ACA.

State Mandates

The ACA contains a provision allowing states to require a qualified health plan in the exchange to offer benefits beyond the defined set of essential health benefits if the state is willing to assume the associated costs.[11] Ms. Bocchino asserted that most state mandates have been enacted without an assessment of scientific evidence. It will be "almost impossible," to include a large number of mandates in the EHB package or require individuals, small businesses, or states that do not currently have these mandates to incur the added cost.

Few states have rigorous reviews like the California Health Benefits Review Program (CHBRP), which evaluates benefit changes proposed by the California legislature before they are mandated. CHBRP assesses the existing scientific evidence related to the proposed benefit and prepares an independent analysis of its medical, financial, and public health impact (Note: this process is further detailed in Chapter 12).

Appeal Processes

Health plans, Ms. Bocchino said, "fully support a fair, robust, and timely process for consumers to appeal benefit denials through external review administered by independent third-party review organizations" as required under the ACA. She urged the committee to review the interim final rule (U.S. Department of the Treasury et al., 2010). The committee's work, she said, should stay consistent with the direction of that regulation.

Principles for Defining and Updating the EHB

Ms. Bocchino outlined principles she believes should drive the definition of the EHB:

- Provide access for consumers to the appropriate care at the right time and in the right setting.
- Ensure that the processes, principles, or criteria are rigorously evidence-based and free from political influence.
- Consider cost-effectiveness, quality, and appropriateness. The process should consider the findings of comparative effectiveness research (CER), including the work of the Patient-Centered Outcomes Research Institute (PCORI).
- Focus definition on the categories of service already established in the ACA, rather than being "too specific" about covered services, which could risk undermining affordability.
- Establish a consistent decision-making process that includes independent analysis and explicit guidelines that consider medical efficacy, and social and financial impacts.
- Balance the comprehensiveness of benefits against ensuring that coverage is affordable. Consumers should have a choice of products that meet their individual needs or desires.
- Minimum thresholds should allow for innovation in benefit design and meaningful differentiation to provide consumer choice across the bronze, silver, gold, and platinum plans.
- Survey the marketplace to further understand what is equal in scope under a typical employer plan (beyond the ACA requirement that the DOL survey employer plans). Initially, this survey should focus on the scope of benefits offered by smaller companies to more accurately represent the needs of the exchange-based market.
- Evaluate all benefits on a *de novo* basis rather than with the frequency and process used to evaluate state benefit mandates.

The process for defining EHB, Ms. Bocchino said, should focus on the degree of specificity included in the Massachusetts exchange and FEHBP program. These benefit packages only specify general categories of service and not the number or frequency of services covered. FEHBP provides guidance relative to the categories of services, but allows individual plans, when they bid competitively, to further define how frequently those services

[11] Patient Protection and Affordable Care Act of 2010 as amended. Public Law 111-148 § 1311(d)(3)(B)(ii), 111th Cong., 2d sess.

will be provided and if there are any limitations on those services. This flexibility, Ms. Bocchino argued, allows for a more competitive market for consumers to make decisions.

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7

Examining Two Categories of Care in Section 1302

Section 1302 of the Patient Protection and Affordable Care Act (ACA) outlines 10 broad categories of care that, by 2014, must be included as essential health benefits (EHB) in any qualified health plan (QHP). Although time constraints prohibited the committee from hearing testimony related to each of these categories in detail,[1] two specific categories, about which many questions had been raised, were investigated: mental health and substance use disorder services, including behavioral health; and rehabilitative and habilitative services and devices. Dr. Kenneth Wells and Dr. Kavita Patel from University of California, Los Angeles (UCLA) and Mr. Paul Samuels from the Legal Action Center (LAC) and the Coalition for Whole Health emphasized the need for:

- Reasonable access to a range of evidence-based mental health and substance use disorder services, as called for under federal parity provisions;
- Treatment that recognizes the chronic, not just acute, dimensions of these illnesses; and
- Collaboration and integration of services across the mental health, substance disorder, and physical health sectors.

Mr. Peter Thomas from the Consortium of Citizens with Disabilities (CCD), Dr. Gary Ulicny from the American Congress for Rehabilitative Medicine (ACRM), and Ms. Marty Ford of The Arc and the United Cerebral Palsy (UCP) Disability Policy Collaboration focused on the need to develop criteria for the EHB package that ensures people with disabilities and chronic conditions can access rehabilitative and habilitative services and devices that help them improve, maintain, and limit deterioration of function. The committee's work, these latter panelists argued, will determine whether plans in the exchanges meet the needs of people confronted with illness, injury, disability, or other health condition by enabling them to become more healthy, functional, and independent.

PRESENTATION BY DR. KENNETH WELLS, DAVID GEFFEN SCHOOL OF MEDICINE, UCLA

Dr. Wells began by emphasizing that the delivery of behavioral health services in the United States is "extremely problematic." Stigma, he said, prevents people from seeking needed care. Additionally, the "private

[1] See Chapter 9 for brief presentations related to other categories. Additional written testimony related to each category has been received from other parties through the IOM committee's online public comment form and other means.

sector does not have the infrastructure to care for more severe mental disorders" because "most people with severe and persistent illness are primarily in the public sector." These problems are compounded by poor information systems, a lack of clinical decision support and data analysis, and a lack of availability in the market of many established, evidence-based treatments. Individuals with schizophrenia, for example, benefit from evidence-based family psycho-education in addition to medication (UNC School of Medicine, 2011). Yet, Dr. Wells said, many people with schizophrenia in outpatient specialty mental health settings do not get adequate family psychosocial management in practice; most of this family management is informal rather than following evidence-based practices (Dixon et al., 2001; Young et al., 1998), and few families are referred to evidence-based family psychosocial treatment even when it is available (Cohen et al., 2010).

Science should inform the provision of services and help define future research questions, he said. However, there is a lack of adoption of evidence-based psychosocial treatments for many behavioral health disorders, especially in primary care, which tends to focus on medication management strategies. Furthermore, demonstrated competence in delivering a wide range of evidence-based psychosocial treatments is not necessarily a requirement of professional training programs. With more limited insurance reimbursement for behavioral health services, incentives have been poor for improving the market for delivering such services. With the passage of parity legislation and requirements to cover behavioral health services in the EHB package under insurance exchanges, Dr. Wells suggested that it was "time for a wide range of evidence-based treatments and system-based quality improvement interventions, to be viewed as essential benefits." In addition, he suggested that in areas where evidence is limited but the need for services is great due to the severity of illness, benefits should include services that meet reasonable community practice standards.

Many persons with behavioral health needs can have difficulty obtaining care and finding providers in a timely manner even when they have private insurance (Wang et al., 2005). Furthermore, behavioral health conditions have their roots in both biological and social factors, and this requires a range of biological and psychosocial treatments. Current mental health and substance abuse providers for safety-net populations will likely be the only available, initial source of care even as low-income populations transition to the private insurance market or into the expanded Medicaid program. These providers have expertise in managing this population. In addition to covering such providers to have adequate capacity for expanded services, the covered services should include the necessary range of services (including psychosocial services outside of the traditional medical model) to improve outcomes, especially for severely ill populations. Otherwise, Dr. Wells argued, "we will continue to have people who are vulnerable, do not necessarily understand the conditions they have, and will not receive the best evidence-based care." It is key, he said, that the full set of providers and service settings be eligible for reimbursement, thus requiring a broadening of insurer views of eligible providers and services, which in turn should lead to an improved market environment for the availability of evidence-based services.

Additionally, Dr. Wells suggested that individuals should be able to access care "for all of their illnesses." This is especially important, he said, for people with behavioral health conditions because they have a higher prevalence of physical health conditions (De Hert, 2011; Goodell et al., 2011). Largely because of co-morbid medical conditions, people with schizophrenia have a life expectancy 20 years less than those without schizophrenia (Goodell et al., 2011; Wildgust et al., 2010), while people with bipolar illness have a 15-year shorter life expectancy (Roshanaei-Moghaddam and Katon, 2009), and people with depression also have reduced life expectancy (Schulz et al., 2000). Cost effectiveness for mental health and substance use services "has to be thought of differently," Dr. Wells explained, to include the effects of treatments on reducing societal costs of illness, including premature mortality and morbidity (Schoenbaum et al., 2001; Wells et al., 2000). Behavioral health conditions are prevalent across the lifespan, have a relatively early age of onset, and tend to have long-term health and social consequences, including across generations in the same family (IOM, 2009). These factors increase the importance of assuring that affected individuals and families have access to the range of services needed to improve outcomes early in the course of illness and over time.

The Mental Health Parity Act and the Affordable Care Act

The Wellstone Domenici Mental Health Parity and Addiction Equity Act[2] "fundamentally changed the landscape" of many health insurance markets by requiring mental health and addiction services, when offered, to be under equivalent terms of coverage to those services covered for medical conditions. The focus on coverage parity was further extended by the ACA. Because of the Parity Act, typical private insurance is currently in a state of flux regarding the coverage of mental health and substance use care to conform with that law, as well as interim regulations issued by the U.S. Department of Health and Human Services (HHS), which require parity of coverage in terms of both quantitative limits such as co-payments or co-insurance rates, and non-quantitative limits such as preauthorization and benefit management strategies. The current market, Dr. Wells said, "is already changing and will be changing rapidly over the next three years," so HHS will need to look beyond the historical data on benefit policies in typical employer plans to find a benchmark benefit plan.

Dr. Wells pointed out that outpatient medical expenditures for mental health as a percentage of gross domestic product (GDP) have not increased over the last 10 years (Frank and Glied, 2006; Glied and Frank, 2009) because mental health care has been so extensively managed. "People are not rushing in to get this kind of care," he said, "because if you have to get pre-authorized every four visits, how many of those pre-authorizations will be approved for evidence-based psychotherapy for depression?" Instead, the market has "tilted away from psychosocial treatments to medication-based treatments."

Dr. Wells concluded by expressing that the design of the EHB package "is an opportunity to truly shift the paradigm of mental health care." "We have an opportunity," he said, to define services as essential, rather than only providing a "minimum" set of services, which has been the case in mental health care. Additionally, Dr. Wells urged the committee to think of the long-term and social costs of untreated mental health problems, which society tends not to think about until there is a tragedy.

PRESENTATION BY DR. KAVITA PATEL, UCLA SEMEL INSTITUTE

Dr. Patel used her experience working on health insurance policy for Senator Ted Kennedy and the Obama administration, as well as her knowledge of the Massachusetts reform efforts as an avenue for explaining the unique nature of mental health and substance use benefits. Her view of Congress' intent in crafting Section 1302 of the ACA was that there was no desire to incorporate the expansiveness of benefits provided in the Medicaid program into the EHB, especially given the heterogeneity across Medicaid programs with respect to behavioral health services. But, she advised the committee to look to Massachusetts' experience with implementation to determine who is likely to enroll (see related general comments on legislative intent and the Massachusetts experience in Chapters 2 and 4).

Lessons from Massachusetts

Most insurers, particularly commercial insurers, will need to consider the unique needs of the populations who will purchase insurance through the exchanges. Massachusetts' experience in covering mental health is that these newly insured people tend to be low-income and racially and ethnically diverse (MA Health Connector, 2009). This population necessitates an infrastructure of community-based behavioral health services. Committee member Mr. Koller supported the importance of examining the Massachusetts experience to "see who the bulk of new enrollees will be in the exchange come 2014," as these will be the first groups subject to the EHB package and many will likely have characteristics similar to the Medicaid population. Dr. Patel concurred, saying that a recent study showed that for outpatient utilization, the newly covered "behaved a lot more like Medicaid TANF [Temporary Assistance for Needy Families] adults" than like the commercially insured, with a resulting increase in emergency room use specifically because of mental health disorders.

[2] Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008. Public Law 110-343, 110th Cong., 2d sess. (October 3, 2008).

The Need for Comprehensive Benefits

The full scope of services necessary to achieve and sustain recovery and prevent behavioral health conditions should be considered essential, Dr. Patel argued. In particular, she said, the committee should ensure that the EHB package devote its attention to case or care management, patient education and activation, and coordination of services for patients who are vulnerable due to illness or social factors. Community-based services, which take place in churches, barber shops, or in lay worker settings, she said, have been shown to be effective in treating mental health, behavioral health, and substance use disorders. Traditionally, she said, these services would not be covered because they would be considered outside the scope and setting of benefits.

Scope, setting, and the range of providers are "critically important" principles that HHS should consider. Dr. Patel used an example of lay community and social case workers to support screening, education, and coping skills for individuals with behavioral health problems in Los Angeles as part of the National Institute of Mental Health's Community Partners in Care study (Chung et al., 2010) and in post-Katrina New Orleans as part of the Mental Health Infrastructure and Training Project (Wennerstrom et al., in press). While lay community workers and case managers have a "long history" of working with patients with various chronic conditions, under the Parity Act, it is possible that they "may be eliminated from being part of the team that provides care." Lay community workers and case managers may be excluded for two reasons:

1. Under the Interim Final Rule and the Parity Act itself, six classifications of benefits are specified: inpatient, in-network; inpatient, out-of-network; outpatient, in-network; outpatient, out-of-network; emergency care; and prescription drugs (U.S. Department of the Treasury et al., 2010). These categories do not necessarily lend themselves to community-based care.
2. Medical necessity determination: parity regulations allow for coverage based on "medical necessity" if care is provided by a licensed health care professional within his/her scope of practice.

She urged the committee to include communities, clients, providers, and patients in the process of determining adequacy and effectiveness of mental health services in a QHP, consistent with the patient-centered spirit of the ACA.

Dr. Patel urged the committee to use benchmarks from the private sector and commercial plans, as feasible, to understand the challenges in designing behavioral health benefits. However, such benchmark programs need to be compatible with the principles and regulations that apply under parity and reform legislation, such as parity of coverage and, for the exchanges, mandated inclusion of substance abuse and mental health services. Further, the benefit designs in such plans may need to be rethought to determine how to provide reimbursement support for a broader range of disorders and services together with incentives to promote quality and efficiency. Plans operating under the parity mandate, such as the Federal Employees Health Benefits Program (FEHBP), may provide examples of covered services and quantitative benefits. Based on plans currently available, though, it will be harder to identify examples of benchmarks under parity for nonquantitative benefits.

Committee member Dr. Linda Randolph indicated that most of the discussion by Drs. Wells and Patel had focused on treatment, and asked for comment on whether plans could or should cover preventive interventions since such interventions are not traditionally provided in medical settings. Dr. Patel acknowledged that "this is where it gets more complicated, because the evidence base is not there," and asked the committee to build flexibility into the process for updating the EHB package so that preventive care can be addressed as evidence develops. Dr. Wells noted that screenings for depression in primary care settings and in school-based clinics provide one potential avenue for consideration. "No one would argue," he said, "with the fact that there is strong evidence for teen suicide prevention strategies through schools" (Eggert et al., 2002). In addition, he said, there are a range of early intervention programs for reducing depressive disorder in high-risk teens (Clarke et al., 2005) and a range of evidence-based substance use prevention interventions, including school programs such as Project ALERT[3] (Ellickson and Bell, 1990).

[3] Project ALERT is a school-based program which focuses on resisting substance abuse in 7th and 8th graders, most specifically tobacco, alcohol, marijuana, and inhalants (Project ALERT, 2011).

PRESENTATION BY MR. PAUL SAMUELS, LEGAL ACTION CENTER (LAC) AND THE COALITION FOR WHOLE HEALTH

Mr. Samuels, the Director of the LAC and co-chair of the Coalition for Whole Health, echoed the previous panelists in saying that the history of stigma and discrimination in mental health and substance use disorders, and the history of inadequate coverage of mental health and substance use benefits, could be partially mitigated by ensuring these services are comprehensively covered in the EHB package. He urged HHS to ensure equality in coverage for mental health and substance use disorder benefits, and to consider a change in how illnesses are characterized. "One of those problems through the years," he said, "has been a focus on these illnesses as acute, rather than chronic, and addressing them only at the beginning and not as they move forward."

Large treatment gaps exist for mental health and substance use disorders, a problem Mr. Samuels credited to "an over-reliance on public funding for care" (Scanlon, 2002). Less than half of the 15 million adults with serious mental illness receive any care, and less than 20 percent of the more than 22 million Americans with substance use disorders receive any care (SAMHSA, 2010b). These untreated illnesses and disorders create co-morbidity problems: 25 percent of hospital admissions are directly related to untreated mental illness and substance use disorders (AHRQ, 2007). Addressing these unmet needs, Mr. Samuels said, "will save lives and huge amounts of money."

In response to a question from committee member Dr. Sabin, Mr. Samuels pointed out that the failure of insurers to adequately cover these services has "cost a lot of money" because when people do not get treatment, they develop "other kinds of problems" (e.g., heart disease or liver failure) when the underlying condition is not addressed. Furthermore, when these services are not covered by private insurance, "the public dollar is being disproportionately tapped into." Fifty-eight percent of all funding for mental health treatment and 77 percent of all funding for substance use disorder treatment is from the public sector (Levit et al., 2008; Mark et al., 2007).

Mental Health and Substance Use Disorder Parity

The ACA requires mental health and substance use disorder benefits to be included as EHB, thus extending the Parity Act[2] to QHPs and new Medicaid eligibles under benchmark and benchmark-equivalent plans. Parity prohibits quantitative limitations that are "more limited than for other types of medical/surgical benefits" (e.g., mental health and substance use disorder services cannot have higher deductibles and co-payments than medical benefits), and it prohibits non-quantitative limitations that are "more severe and more strictly limiting than for medical/surgical" (e.g., medical management techniques cannot be more restrictive for mental health and substance use disorders than they are for medical benefits).[4] Mr. Koller noted that if the Parity Act was completely successful, the list of 10 categories of care included in the ACA would not need to include a separate line for mental and behavioral health as these services would be included in inpatient and outpatient services. "Yes," responded Mr. Samuels, the goal of parity is to eliminate the disparity that is present between physical illnesses and illnesses of the brain and reach the point where people get what they need no matter which kind of illness it is.

Mental health and substance use disorders have long been recognized by health care and scientific experts as preventable and treatable, but law and insurance policy have not granted these disorders the same recognition. "The history of discrimination in coverage of mental health and substance use disorder benefits needs to be remedied," Mr. Samuels said. He expressed his agreement with points made by Drs. Wells and Patel: individuals need to be able to access the type, level, amount, and duration of care they need, including care for relapses. Thus, medical necessity criteria should reflect the chronicity of mental illness and substance abuse disorders.

Criteria and Methods

Mr. Samuels urged the committee to focus on the quality of mental health and substance use care when determining the criteria and methods for defining and updating the EHB package. Work by the Institute of Medicine (IOM) (2005), the National Quality Forum (NQF) (2007), and the Surgeon General (HHS, 1999), he said,

[4] U.S.C. 300gg-5(a)(3)(A)(ii); Interim Final Rule under Wellstone Domenici: 45 CFR Part 146.

confirms that there is a great wealth of evidence-based practices on which the committee can draw. Furthermore, he said, HHS should consider ways to create incentives to utilize evidence-based or consensus-based practices (e.g., utilizing the full continuum of care, matching patients to the appropriate services, and using medications when they are appropriate).

Mental Health and Substance Use Disorder Benefits

Broad and robust benefits for mental health and substance use disorders would provide access to prevention, wellness, chronic disease management, habilitation, rehabilitation, and recovery at the clinically appropriate level, type, and amount of care; thus, participating plans, Mr. Samuels said, should be required to provide a robust set of benefits in each category of care outlined in the ACA. Additionally, benefit packages should not arbitrarily exclude certain types of services (e.g., excluding residential or non-hospital inpatient services, not covering appropriate medications). Mr. Samuels advocated for an EHB package that includes services, interventions, and strategies to prevent, intervene early, and treat people with these illnesses by helping them achieve and maintain long-term wellness. Research shows that delaying the age of initiation of alcohol and other drug use, for example, will delay and often prevent alcohol and drug addiction in the future (SAMHSA, 2010c). There should also be, Mr. Samuels noted, ongoing support to help people manage their disease over the course of their life, services for children and families, and services that are culturally appropriate. A robust EHB package would:

- Include a full range of services provided at parity with other medical/surgical benefits;
- Manage benefits using good clinical judgment;
- Ensure decisions about the type and amount of care are driven by the treating professional, not payers or other third parties;
- Provide care to individuals and family members over their lifetime;
- Use process measures, such as those developed by the NQF, and outcome measures to ensure care focuses on the patient's quality of life and ability to function;
- Consider the individual treatment needs of the patient and the availability of evidence-based practices as part of medical necessity determinations;
- Change the practice of unfair and inappropriate denials of care; and
- Clearly define and make available to patients and providers the medical necessity criteria and reasons for denial.

In addition to these services, Mr. Samuels noted, individuals suffering from mental health and substance use disorders need access to rehabilitative and habilitative services as many of these individuals lack skills, housing, education, and social supports.

Mr. Samuels advised the committee to look at the Substance Abuse and Mental Health Services Administration (SAMHSA) publication titled *Description of a Good and Modern Addictions and Mental Health Service System* (SAMHSA, 2010a). SAMHSA is currently working with stakeholders and researchers to identify the best services, interventions, and strategies to prevent disease and help individuals with illness achieve and maintain long-term wellness. Other issues facing these fields include workforce development, licensing and credentialing issues, and the delivery of physical and mental health services in a more integrated way.

As the committee develops a process and criteria for defining and updating the EHB package, Mr. Samuels suggested establishing regular working groups of mental health and substance use disorder service providers, consumers, and state directors of mental health, substance use disorder programs, and Medicaid programs. The feedback of these individuals will help ensure the criteria facilitate innovation and account for promising practices that may not yet have a research base. To "redress the history of discrimination in managing benefits," HHS, he said, should make sure that people not only have coverage for these services, but also access.

Question & Answer Session

Mr. Koller asked the panelists to what extent parity is about benefit definition and to what extent it is about benefit administration. In addition to coverage decisions, Mr. Koller said, the standards for network development must also be in place. Dr. Patel concurred, noting that benefit administration is "an art." While a lot of benefit issues are related to administration, not definition, the committee can have an impact, she said, by defining the elements of the benefit design and explicitly noting that the administration of the design is an important consideration, especially for behavioral health, which has traditionally been subject to numerous carve-outs.

Mr. Samuels stated that in the absence of good benefit administration, individuals with mental health and substance use disorders, including people who are homeless, unemployed, and in the criminal justice system "could easily fall through the cracks." We know that a disproportionate share of people who are uninsured have mental illness and substance use disorders (Wu and Ringwalt, 2005), and this has remained the case even after health reform in Massachusetts, Maine, and Vermont (NASADAD, 2010).

Dr. Wells added that defining EHB for this population provides the opportunity to also improve some of the "market problems" that have limited access to evidence-based treatment (e.g., for case management and collaborative care). A recent study showed that integrated collaborative care for depression and chronic medical conditions (heart disease and diabetes) improved outcomes for both types of conditions (Katon et al., 2010). Although collaborative care for depression is typically not covered, other 10-year outcome data indicate that vulnerable populations with depression who receive access to collaborative care continue to do better than their counterparts not initially under collaborative care, long after they may stop seeing their provider; this suggests that they have learned how to better manage their own symptoms and illness due to their initial experience with collaborative care (Wells et al., 2008). These findings indicate that given reasonable, initial attention to patient learning, patients do not have to be "micromanaged through the health care system for a decade" in order to have better outcomes. Dr. Wells stated that there is currently "enormous variation in how mental health and substance abuse is handled" by state Medicaid programs. The EHB will help ensure parity by "leveling the playing field" in some of these plans, which "is a huge change, especially for substance abuse."

PRESENTATION BY MR. PETER THOMAS, CONSORTIUM FOR CITIZENS WITH DISABILITIES (CCD)

Mr. Thomas began a panel that focused on the need for comprehensive benefits for rehabilitative and habilitative services and devices. First, he provided formal definitions of these terms, as well as legislator's statements on the meaning of these terms[5,6]:

- **Rehabilitation therapies** are provided from a continuum of accredited programs and treatment settings based on the intensity of service that helps *improve, maintain, and prevent deterioration* of function (settings include inpatient rehabilitation hospitals, long-term acute care hospitals, skilled nursing facilities [SNFs], long-term residential transitional rehabilitation programs, outpatient therapy, home care, and community-based programs).
- **Habilitation therapies** are services or supports that enable a person with a significant disability to *acquire, retain, improve, or prevent deterioration* of activities of daily living (ADLs) or instrumental activities of daily living (IADLs) over time.[7]

[5] Congressman Pascrell, a co-chair of the Congressional Brain Injury Task Force, included the following in his House floor statement: "The term rehabilitative and habilitative services includes items and services used to restore functional capacity, minimize limitations on physical and cognitive functions, and maintain or prevent deterioration of functioning as a result of an illness, injury, disorder or other health condition. Such services also include training of individuals with mental and physical disabilities to enhance functional development" (Pascrell, 2010).

[6] Congressman George Miller, the Chair of the Committee on Education and Labor, explained that the term rehabilitative and habilitative devices "includes durable medical equipment, prosthetics, orthotics, and related supplies." Miller also stated that "it is my expectation 'prosthetics, orthotics, and related supplies' will be defined separately from 'durable medical equipment." In addition, Congressman Miller explained, "I also expect that durable medical equipment will not be limited to 'in-home' use only" (Miller, 2010).

[7] Italics added to aid comparison.

- **Durable medical equipment (DME)**, prosthetic limbs, orthopedic braces, and other assistive technologies improve, maintain, and limit deterioration of function in mobility, communication, hearing, and vision.

While there is some overlap in definition, habilitation therapies are distinct when they relate to the acquisition of function. Mr. Thomas advised that a sparse EHB package could result in employers eroding their current benefit packages and noted that in the EHB debate, there was recognition that people with disabilities and chronic conditions have greater health care needs. The ACA not only requires coverage of rehabilitation and habilitation services, but also mandates that the EHB package ensure an "appropriate balance," "non-discrimination," and non-denial on the basis of a present or predicted disability. He advocated for a transparent process in which the EHB package would be certified on an annual basis by the Secretary of HHS based on recommendations by a federal advisory body.

Typical Employer Plans

Mr. Thomas explained that most private plans cover rehabilitation services and devices. Both the preferred and standard options of the FEHBP, for instance, cover rehabilitation in a variety of settings at different levels of intensity. Furthermore, the plans cover DME and prosthetics and orthotics. While they have "various types" of exclusions and limitations, "the vast majority of these benefits are routinely covered by health plans, and certainly by public programs." Nevertheless, the U.S. Department of Labor's (DOL's) attempt, Mr. Thomas said, to accurately quantify the typical employer plan's coverage of these benefits will be seriously hampered because the DOL lacks the essential authority and resources to collect detailed data on what employer plans cover. Instead, the department depends on voluntarily submitted plan descriptions that vary in length, scope, and transparency. It is unlikely the DOL report (see Chapter 2), Mr. Thomas argued, will provide a complete understanding of rehabilitation and habilitation coverage provided under the typical employer plan. Rather, HHS will need to acquire supplemental information about typical employer plans.

PRESENTATION BY DR. GARY ULICNY, THE SHEPHERD CENTER

Dr. Gary Ulicny, President of the Shepherd Center, spoke on behalf of the members of the American Congress of Rehabilitation Medicine (ACRM) and cautioned the committee against establishing a rigid or too narrow benefit package for rehabilitation and habilitation because these patients "come with distinct needs running the gamut" from needing to regain function after a fracture to catastrophic brain injuries. Yet arbitrary limits on physical therapy benefits, outpatient therapy, and DME spending are typical of current plans, regardless of diagnosis and individual need (e.g., 30-day inpatient stay, DME cap, outpatient therapy visits) and often "impede the provider from giving the best treatment regimen." Limits, he said, should not be based on arbitrary monetary caps. Instead, benefit design should be based on medical necessity and coverage limitations should be based on evidence, not the cost concerns of plans.

Return on Investment

Rigid or narrowly defined benefit packages are often not cost-effective because they are shortsighted, he emphasized. Determination of benefits should focus on the return on investment based on the reduction in long-term disability and dependency. Given some of the ACA's proposed changes (e.g., the elimination of lifetime caps and the portability of insurance), these long-term costs will become more important to both government and the private insurance market. In today's health insurance market, Mr. Ulicny said, a patient may be unable to receive a medically necessary service if it is not expressly included in their health insurance policy. Plans should have the flexibility to cover extra-contractual services when they meet the recovery needs of the individual patient and provide substantial return on investment.

Furthermore, he suggested that when discussing affordability, in addition to the cost of the service, HHS should consider long-term savings associated with the prevention of secondary conditions and deterioration in function,

in addition to the cost of the service. For example, he said, a person with a spinal cord injury who is denied coverage for an appropriate wheelchair may, in two years time, develop a skin breakdown that requires expensive reconstructive surgery to repair. In this case, the appropriate (and perhaps more expensive) wheelchair would have been a cost-saving investment. The ultimate outcome of rehabilitation is an improvement in the patient's function. In some instances, traditional definitions of medical necessity do not appropriately weight the importance of functional improvement. Too often, he said, insurers apply medical necessity without considering the long-term functional and health benefits to the patient of a service or device. And in many instances, these decisions lead to much greater disability and long-term dependency costs to the system.

Criteria and Processes

Current reimbursement models, Dr. Ulicny stressed, do not incentivize good outcomes: "We get paid for doing more, we do not get paid for doing better, and I think that is something that needs to be inherently changed." The design of the EHB package, he argued, can play a role in incentivizing providers to "do the things that are right and produce meaningful outcomes."

Dr. Ulicny noted that "although we cannot overly rely on randomized clinical trials," the committee should establish evidence-based criteria for updating the EHB package by recognizing the value in clinical replication (Level II and III evidence) and utilizing expert consensus. In rehabilitation, large teams of providers make it difficult to tease out the effectiveness of each piece of intervention.

In sum, he suggested HHS:

- Include items and services that assist in regaining and maintaining functional capacity and preventing deterioration,
- Include a mechanism for individualizing benefits,
- Ensure limitations and exclusions for rehabilitative and habilitation benefits are evidence-based,
- Establish a formal advisory committee, including consumers, to advise the HHS Secretary on benefit design and related issues, and
- Consider alternative reimbursement strategies that encourage good performance.

The committee, he suggested, should "veer away from using Medicare as a benefit design model" for the rehabilitative and habilitative services covered in the EHB because Medicare is designed primarily for people over age 65 and its benefit design will not adequately take into account the needs of, for example, a 15-year-old who has experienced a catastrophic spinal cord injury.

Role of Device Manufacturers

When committee member Dr. Santa asked to what degree the benefit design should "try to make the behavior of device companies more functional in terms of pay for performance and outcomes, Dr. Ulicny stated that "the problem with the device industry is that the device is released far before we are able to provide a measurement of its functional improvement capability." The lack of information about functional improvement, Dr. Ulicny said, is something to address "as we begin to look at what things are most appropriate, whether it is the intensity of the service or the device itself." In lieu of functional improvement information from device manufacturers, the industry, Dr. Ulicny said, has its own "self-leveling process." Providers, for example, did not endorse a $22,000 wheelchair because providers thought it unaffordable for most individuals and that the "additional benefit was not worth the cost." Without provider endorsement, production of this particular device stopped.

PRESENTATION BY MS. MARTY FORD, THE ARC AND UNITED CEREBRAL PALSY DISABILITY POLICY COLLABORATION

Ms. Ford, who spoke on behalf of the Long Term Services and Supports and Health Task Forces of the CCD, began by stating that Medicaid defines habilitative services as those services designed to assist participants in acquiring, retaining, and improving the self-help, socialization, and adaptive skills necessary to reside successfully in home and community-based settings.[8] These therapies, services, and supports, which are needed over the course of a person's lifetime, enable people with significant disabilities to learn, improve, or prevent deterioration of activities of daily living. Habilitation therapies, she said, include occupational, physical, speech, and behavioral therapies, along with other services and supports. Ms. Ford noted that habilitation services can prevent costly institutionalization; help people function better in the community; prevent frequent hospitalization and emergency room visits; build social, communication, and personal hygiene skills; and facilitate behavior and medication management.[9]

Definitions

"One of the issues" in coverage of habilitation services, Ms. Ford stated, is that it is often unclear why a distinction between habilitation and rehabilitation is made. The distinction used to determine coverage is often whether the person is learning something for the first time or whether they are re-learning something following an accident, injury, or medical event. When this distinction is made, she said, a person "learning something for the first time" is often not covered for the service. If a person has severe developmental disabilities, teaching the person the fine motor coordination needed to get dressed is considered habilitation and not typically covered under private insurance, whereas if the person had a stroke, teaching him these skills is considered rehabilitation and would be covered. Ms. Ford further illustrated the distinction with two additional examples:

- The services provided by a speech therapist to a 3-year-old child with autism are considered habilitation because the child has never spoken. The services provided by a speech therapist to a 3-year-old to regain speech after a traumatic brain injury are considered rehabilitation. There is no difference, Ms. Ford said, in the child's need for that service.
- A strength-training program for a person with a congenital spine condition is considered habilitation, whereas a strength-training program for a person with a spinal cord injury is considered rehabilitation. Again, she said, there is no difference in the patient's need for that service.

Acquiring, retaining, and improving skills can be both habilitative and rehabilitative, depending specifically on the needs of that individual.[10]

Legislative Intent

Children and adults with disabilities and significant health needs require both habilitative and rehabilitative services and supports. Ms. Ford argued that the discrimination against children and adults who need these services

[8] U.S.C. Title 42 § 1915(c)(5)(A).

[9] When states propose to provide services under the Home and Community-Based Services Waiver (including habilitation services), CMS reviews the proposed services to ascertain whether the service: contributes to the community functioning of waiver participants and thereby avoids institutionalization; is reasonably related to addressing waiver participant needs that arise as a result of their functional limitations and/or conditions; and/or falls within the scope of Section 1915(c) of the Act and is not at odds with other provisions of the Act (CMS, 2008, p. 127). Note: By definition, for coverage under the waiver, habilitation services must be capable of reducing institutionalization and assisting people to function better.

[10] Another speaker pointed out that habilitative services differ from rehabilitative services in that they do not serve to improve the patient to a pre-illness or injury state, and therefore, do not always have a clearly defined endpoint in either time or scope of services. Without some limitations, these services (e.g., for autism) can substantially increase costs and lead to unaffordability and adverse selection in the insurance market, said Ms. Ehnes in her presentation. Additionally, insurers have traditionally set definable and predictable parameters to exclude coverage of non-medical services (see Chapter 12) (DMHC, 2011).

denies them access to medically necessary and appropriate interventions. Members of Congress, she said, are very familiar with the term habilitation from its use in the Medicaid program, and, as indicated in floor statements, Congress clearly intended to include habilitation services and supports in the EHB package.[5,6]

As stated in the ACA, the category of rehabilitative and habilitative services and devices is a broad category that, since combined, indicates that acquiring and retaining function are critical aspects of the benefit category.

State Mandates

Many states, Ms. Ford noted, have "recognized the importance of habilitation" by requiring private insurers to provide these services. Of the 23 states that passed statutes requiring coverage of benefits for people with autism spectrum disorders, 14 have used the term habilitative and rehabilitative care in the legislative language (NCSL, 2010a). In many states, she said, the term habilitative is defined as "any professional counseling and guidance service and treatment program, including applied behavior analysis that is necessary to develop, maintain and restore, to the maximum extent possible, the function of an individual" (Autism Speaks, 2011). Additionally, she said, many of these state mandates specifically require coverage of a broad list of therapies including occupational, physical, speech, and behavioral therapies (NCSL, 2010b).[11]

Illinois and Maryland have mandated health plans to provide habilitation services to children under age 18 with congenital, genetic, or early acquired disorders (Illinois Department of Insurance, 2010; Maryland Insurance Administration, 2009). Since 2000, Maryland has tracked the economic impact of the state mandate and found that the mandate costs two dollars of the average annual group health insurance policy premium, or 0.04 percent (Rosenblatt, 2007).

Building an Evidence Base

When committee member Dr. Ho asked how, in the absence of an evidence base for some of these services, plans should make medical necessity determinations, Ms. Ford responded that rehabilitative and habilitative services are "always based on an individualized plan of care" and that medical decisions are often based on decisions by patients, their families, and their health care provider. It would therefore be a mistake, she said, to "not take clinical expertise into account" when making medical necessity determinations. Mr. Thomas supported Ms. Ford's argument while also noting that "you go with the highest level of evidence that you have." While the evidence base for rehabilitative services has developed significantly, it is "still a work in progress," Mr. Thomas said. Some medical necessity determinations, he noted, are obvious even without clear evidence: a randomized controlled trial (RCT) is not necessary, for example, to understand that providing an artificial limb to someone without limbs will improve function. Level I, RCT studies are not practical for many rehabilitation services and devices, he said, so "there must be a different way to approach the evidence base." Mr. Thomas added that hospitals and payers often use proprietary rehabilitation treatment guidelines (e.g., McKesson's InterQual® guidelines and Milliman Care Guidelines®), which he described as "quite unrealistic in many instances." Despite not being "particularly well evidence-based," he said, they are often overly restrictive and rigidly applied.

Dr. Ulicny noted that the Shepherd Center is part of a national study to measure outcomes of therapy sessions. After every session, therapists use a hand-held computer to enter what they did with the patient and the outcome of that particular session. This study, which is being conducted across six model centers, may help build an evidence base, he said.

In lieu of this evidence, Dr. Sabin asked the presenters for examples of "clinically wise and ethically admirable managed care" in their fields. The American Physical Therapy Association, Dr. Ulicny noted, has developed an evidence-based database that makes available clinical decision-making support to providers. Additionally, Dr. Ulicny said, workers' compensation programs are historically good at using processes and tools to make what Dr. Sabin described as "clinically well-informed and ethically admirable" decisions. The workers' compensation

[11] Others have pointed out that, in general, health insurance contracts cover only "medical" services. These contracts do not cover all potentially beneficial services (DMHC, 2011).

model, Dr. Ulicny said, uses external case management, utilization management, and a collaborative approach with payers. This process ensures the workers' compensation program does "what is best for the patient and family, the payer, and the provider."

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8

Non-Discrimination in the Required Elements for Consideration[1]

PRESENTATION BY MS. SARA ROSENBAUM, THE GEORGE WASHINGTON UNIVERSITY

Ms. Rosenbaum, Chair of the Department of Health Policy and Health Services at the George Washington University School of Public Health and Health Services, provided the committee with additional insights into "what kinds of issues were on the minds of lawmakers" as they drafted the "required elements for consideration" portion of Section 1302.[2] These required elements for consideration, she said, were not included in the committee versions of what became the final statute. Instead, these provisions were added when Senate Majority Leader Harry Reid assembled the final Senate bill that was ultimately signed into law. On the House side, members and staffers expressed concern about having protections for people who have greater than normal health care needs. Ms. Rosenbaum noted that the required elements are not part of the benefit entitlement itself. Rather, the inclusion of the required elements was a directive to the Secretary of the U.S. Department of Health and Human Services (HHS) to articulate standards for benefit design and coverage determinations to modify "what has been historically at the discretion of insurers." Specifically, this section of the law addresses having balance among categories of care and not having coverage decisions, reimbursement rates, incentive programs, or benefits that discriminate based on age, disability, or expected length of life. This discretion relates not only to individual medical necessity decisions, but also to coverage design at the macro level.

Ms. Rosenbaum noted it is very unusual for federal law to "deal with the content of health insurance" from a regulatory viewpoint. The Patient Protection and Affordable Care Act (ACA) echoes Medicaid's heretofore unique nondiscrimination rule.[3] Even the Americans with Disabilities Act of 1990 (ADA)[4] "does not deal with the content of health insurance," an issue addressed in a leading federal case whose decision was allowed to stand by the U.S. Supreme Court.[5] Furthermore, the Supreme Court has expressly held that Section 504 of the Rehabilitation Act,[6]

[1] Financial support for development of analyses in Ms. Rosenbaum's statement comes from The Commonwealth Fund in conjunction with development of an expanded article on the subject published subsequent to this presentation (Rosenbaum et al., 2011).

[2] Patient Protection and Affordable Care Act of 2010 as amended. Public Law 111-148 § 1302 (b) (4), 111th Cong., 2d sess. (See Appendix A for Section 1302 in its entirety.)

[3] Code of Federal Regulations, Title 42 Section 440.230(c) barring nondiscrimination in the provision of required services on the basis of condition.

[4] U.S. Code, Title 42 Sections 12101 et. seq.

[5] *Doe v. Mutual of Omaha Insurance Company,* 179 F.3d 557 (1999) cert. den. 528 U.S. 1106 (2000).

[6] The Rehabilitation Act of 1973, Public Law 93-112 § 504 (September 26, 1973).

which relates specifically to Medicaid and is the predecessor statute to portions of the ADA, similarly does not reach the content of health insurance.[7,8]

A key question for HHS is to consider how to comment on the use of limits—which are prevalent in benefit plan administration—given the ACA's intent to reform insurance industry practices, she said. Health insurance coverage entails legal and financial risk. For this reason, insurers logically seek to structure their products to provide risk exposure protection against the covered population. These risk avoidance techniques, however, go well beyond strategies for assuring that insurance pays only for medically necessary care. Ms. Rosenbaum cited an example of a once prevalent, but now precluded intoxication exclusionary clause from when many believed alcoholism was a behavioral choice not a medical condition: if the injury or the illness was related to intoxication, the plan would not provide coverage on the grounds of this "morals clause" (Rosenbaum et al., 2004). She urged the committee to keep this example in mind when developing recommendations for the Secretary. She clarified that it is necessary to put some limits on what is a covered treatment, but she believes the ACA is trying to convey that insurers cannot come up with treatment distinctions by labeling underlying conditions in ways that push specific individuals outside of the scope of the contract.

Under the ACA, the Secretary has the primary responsibility for setting up a federal framework for essential health benefits (EHB) coverage, but Ms. Rosenbaum opined that the Secretary may decide on a framework that delegates a "fair amount" of authority back to plans. For example, the Secretary could conceivably instruct insurers and plan administrators to utilize the terms and definitions in their most popular group health products as long as such terms and definitions do not discriminate on the basis of disability by, for example, defining a benefit as covered only in cases in which restoration or recovery are possible. This approach to tempering delegated authority is consistent with other laws, such as the Mental Health Parity Act,[9] which gives insurers and health plans discretion over whether to cover mental illness and substance use disorder benefits but prohibits the use of discriminatory quantitative and non-quantitative coverage limits. "It is wrong," she said, "to conclude that the essential health benefit statute leaves the status quo in play. The essential benefit statute is an enormous, profound departure from the way in which we've conceptualized the discretion of insurers, but that is not to say that [the Secretary] could not specify a fair and nondiscriminatory framework and process to avert discrimination in benefit design and making coverage determinations."

Arbitrariness

The clearest precedent for the prohibitions against discrimination in the EHB statute can be found in the Medicaid statute. Since the Medicaid statute's original enactment,[10] its "reasonableness" provision[11] has been understood by both the agency[12] and the courts[13] as barring arbitrary limits in required services based solely on an individual's condition, diagnosis, or type of illness. Furthermore, at least two recent court decisions suggest that at least some courts will reject coverage denials under Medicare where the basis of the denial is the arbitrary exclusion of otherwise covered services based on absence of "recovery" potential.[14]

The required elements for consideration provision of Section 1302, Ms. Rosenbaum argued, is designed to address the issue of insurer discretion to discriminate against certain types of conditions in the context of benefit design and coverage determinations. In some cases, excluded conditions may be quite specific, while in others, a proxy of "recovery" or "restore" is commonly used to differentiate chronic conditions for which there may be

[7] U.S. Code, Title 29 Section 794.

[8] *Alexander v. Choate,* 469 U.S. 287 (1985).

[9] The Mental Health Parity Act of 1996, Public Law 104-204, 104th Cong., 2d sess. (September 26, 1996).

[10] The precursor to the federal non-discrimination rule can be found in the Handbook of Public Administration, Supplement D, issued in 1966 by HEW.

[11] U.S. Code, Title 42 Section 1396a(a)(17).

[12] U.S. Code of Federal Regulations Title 42 Section 440.230(c).

[13] See, for example, *Pinnecke v. Preiser,* 623 F. 2d 546 (8th Cir. 1980).

[14] See, for example, *Papciak v. Sibelius*— F.Supp. 2d —, 2010 WL 3885605 (W.D. Pa.). and *Anderson v. Sibelius*, F. Supp. 2d, 2010 WL 4273238 (D.Vt.).

no "recovery," from those that are acute and time-limited and for which recovery is possible. Disability and age both raise this issue, since age can affect the potential for recovery. The presence of developmental disabilities can also trigger "recovery" discrimination. The question should be whether treatment aids functioning and serves to maintain health or avert deterioration in health, not whether recovery can be expected.

For age: The statute bars discrimination, but not the use of patient characteristics when such characteristics rest on a reasonable clinical and scientific evidentiary base. A decision cannot be made "on the basis of age," but a decision based on clinical factors (age is a recognized clinical factor when, for example, age is used to determine when to immunize a child against certain diseases) would not be a decision based on age.

For disability: Limits that require recovery or restoration inherently discriminate against individuals for whom the expected impact is the attainment of, improvement in, or maintenance of function, or the aversion of functional loss. Exclusionary clauses that limit coverage only to situations in which recovery can be expected create insurmountable problems for individuals who would benefit from medical care but for whom recovery is not possible. Similarly, exclusions that depend on whether the need for treatment also has been noted in an employment plan, individualized education plan, or some other document addressing the work-related, social, developmental, or educational needs of a patient could be considered discriminatory. The central question is whether the treatment is medical in nature and whether the individual can be expected to medically benefit from the treatment. The fact that the health benefit will have spillover effects in educational, employment, or social contexts should be irrelevant to the coverage determination.

For expected length of life: In the case of hospice treatment, for example, where length of life is accepted as a core element of the intervention, length of life might be a proper consideration. On the other hand, the ACA withdraws expected length of life as a criterion where reasonable clinical and other relevant evidence shows an individual's ability to benefit from a treatment. The concept of "to benefit" encompasses attainment and maintenance of health as well as avoidance of deterioration.

Ms. Rosenbaum made a distinction between what she called "across-the-board limits" and condition-specific limits. Across-the-board limits, she said, apply to everyone in the plan, such as the exclusion of infertility treatments. Such an exclusion does not single out people with disabilities. Conversely, an embedded guideline might state "we cover infertility treatment, but not in situations in which the woman has one of four different conditions." Such flat exclusion without evidentiary consideration of whether the underlying condition is one that impairs the ability to benefit from fertility treatment would be discriminatory. Hospitalization limits of 30 days per spell of illness or 60 physical therapy treatments may limit medically necessary care, but they do so without regard to the underlying condition. Such limits, Ms. Rosenbaum said, fall with particular severity on the sickest members of the coverage groups and are undesirable for many reasons (the most desirable result is, of course, to have enough scientific and clinical evidence to be able to make coverage design and administration decisions solely on the basis of the evidence). But courts have ruled that across-the-board limits on scope are not discriminatory against persons with disabilities under federal civil rights laws, nor, presumably, would across-the-board limits "discriminate" against individuals because of age or expected length of life.

Preventing Discriminatory Definitions

Ms. Rosenbaum suggested the Secretary consider cautioning insurers about using definitions, whether broad definitions for medical necessity or service specific ones, that inherently discriminate on the basis of a condition. A medical necessity standard limited to medical conditions, for instance, could be interpreted as not addressing coverage of treatments for developmental disabilities because they are often not considered medical conditions. There are, however, medical treatments, including speech therapy and physical therapy, appropriate for children with developmental disabilities. "Just because the condition is developmental does not," Ms. Rosenbaum said, "make benefits aimed at alleviating or ameliorating the condition any less medical in nature." The question is whether coverage can be expected to produce a beneficial impact, not whether that impact is "restorative." She believes if an insurer were to exclude medical treatments based on an underlying condition and without regard to evidence from the patient's record and, when available, research evidence, it would be applying a discriminatory definition. Similarly, if an insurer were to define speech therapy as "a therapy that is needed to allow somebody

to recover speech," that definition would be discriminatory as it would withhold therapy from someone who never attained speech. Nor should it be at the discretion of the insurer to decide if therapy for a multiple sclerosis (MS) patient, for example, will be covered to avert a loss of functioning as opposed to recover prior functioning. As a general rule, she said, limitations that discriminate on the basis of an underlying condition should be avoided.

When committee member Ms. Ginsburg asked Ms. Rosenbaum to comment on how one would define "what is medical," Ms. Rosenbaum clarified that despite being "an insurance lawyer" for her entire career, she has "no idea what a medical condition is." It is more helpful, Ms. Rosenbaum said, to "look at the intervention. If the intervention is by a licensed clinical professional, it is regulated under a state scope of practice act governing the health professions." Then, she said, it should be "recognized by insurers as a form of treatment when furnished by a licensed professional acting within the scope of practice."

Committee member Dr. Selby asked whether the committee should be "cautious" about ensuring policies do not discriminate against conditions such as rare diseases for which there is less likely to be convincing, rigorous evidence. Ms. Rosenbaum reiterated that first, one needs to determine "what it means to discriminate" and suggested that her opinion is that discrimination is any "arbitrary distinction" and that may or may not relate to a rare condition. It will be decades, she said, before an evidence base will be available for rational distinctions based on the condition. Until then, she said, "we would really like to move away from condition-based distinctions in coverage . . . to focus on medical management across the board, not just in mental health, but generally, value-based coverage, incentives, yet not draw distinctions based on conditions, or age, or expected length of life."

Committee member Dr. Sabin asked if it would be discriminatory for an insurer, for example, to acknowledge that children with autism spectrum disorders have severe speech delays, but regard those delays as an "educational problem." In response, Ms. Rosenbaum cited a case in which an employer-sponsored plan administrator decided that certain types of treatments for a particular child with developmental disabilities were educational in nature and were therefore excluded from reimbursement.[15] All of the treatments in question were medical treatments furnished by medical professionals in a clinical setting. They were, in Ms. Rosenbaum's opinion, "unquestionably covered medical treatments, except that the child's condition was labeled behavioral and the treatment was labeled educational, and that was the end" of coverage for the child.

Her response prompted Dr. Sabin to argue that some medical treatments, including physical therapy, can be used to enhance, rather than treat, a condition. Ms. Rosenbaum responded that in the absence of expressed exclusions in plan documents, courts have generally resisted efforts to define medically necessary as: (a) limited by the kind of condition or (b) limited by the notion of recovery.[16] Medical necessity, she said, should cover the treatment regardless of whether it will aid in recovery or whether, instead, it is necessary to develop, maintain, or avert loss of a function. She noted the inherent weakness in a definition of medical necessity that is limited to "medical conditions." The phrase "is a mechanism for eliminating certain kinds of conditions that some people do not consider medical."

Committee member Dr. McGlynn noted that when Dr. Mark McClellan was the administrator of the Centers for Medicare & Medicaid Services (CMS) from 2004 through 2006, he attempted to require, that when a treatment lacked evidence, that such evidence had to be generated as a condition of coverage. Is this practice, Dr. McGlynn asked, "inherently discriminatory?" Ms. Rosenbaum stated that Dr. McClellan's attempt "was brilliant." Currently, the disability community faces a dearth of evidence and consequently experiences denials. As suggested by Dr. Gary Ulicny in Chapter 7, she said the rehabilitation treatment community itself is attempting to gather the evidence needed to justify interventions. The population with disabilities and others with heightened health care needs "welcome a greater focus on evidence-based practice and reporting." A review of the case law on coverage suggests that individuals most seriously burdened by health conditions are the most affected by denials, Ms. Rosenbaum said. Their high representation in judicial decisions underscores the enormous costs they face when an insurer or plan administrator denies coverage and the corresponding importance of braving a lengthy and difficult appeals process.

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[15] *Mondry v. American Family Mutual Insurance Company,* 557 F. 3d 781 (2009), 130 S. Ct. 200 (2009).

[16] See, for example, *Bedrick v. Travelers Insurance Company,* 93 F. 3d 149 (4th Cir., 1996) and *McGraw v. Prudential Insurance Company of America,* 137 F. 3d 1253 (10th Cir., 1998).

Treatment Guidelines

Ms. Rosenbaum advised the committee against allowing insurers to embed treatment guidelines in contracts of coverage and plan documents. These normative, undisclosed, and fixed limits on treatment do not allow for any deviation based on underlying condition. As a result, she said, they can be considered essentially definitional. She suggested that guidelines are often not based on evidence; they are simply conclusory statements by an actuarial firm. Furthermore, even if clinically sound, a guideline may be used out of context as a coverage limitation as opposed to an informal guide, where one would weigh other clinical evidence.

When committee member Ms. Monahan asked for more details about how insurers should use evidence-based guidelines regarding disabilities, Ms. Rosenbaum acknowledged that "guidelines may be used completely out of context" to limit coverage. The purpose of these guidelines, she said, is to suggest that certain underlying conditions may inhibit or impair the success of treatment. Guidelines can help inform decisions, but they should not be embedded in plan documents as an actual limitation on coverage. Committee member Dr. Santa followed up on this exchange by asking Ms. Rosenbaum whether she would agree that if "the evidence is more robust, you are immunizing yourself from discrimination, but to the degree the evidence is not robust, then you're susceptible to discrimination." Ms. Rosenbaum concurred, also noting that flexibility can help mitigate against arbitrary distinctions that are often made when the evidence is weak. Flexibility would allow determinations to consider, she said, whether "there is a reasonable basis" for the treatment to be covered, even in the absence of good evidence. Medicaid, for instance, cannot draw arbitrary distinctions solely on the basis of a condition.[17] HHS should also worry about the evidence base to justify inclusions and denials, and often, the evidence-free zone is showing up on both sides.

Ms. Rosenbaum concluded by suggesting the committee be "less worried about the specific terminology and more worried about what the consideration section tries to do." Section 1302(b)(4) of the ACA provides "required elements for consideration" and tries to "bring some balance to content limits on coverage." The ACA is trying to prevent discriminatory types of limitations and exclusions (i.e., that are not solely determined on the basis of age, expected length of life, or disabling conditions) in favor of limits that are reasonable.

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9

Additional Stakeholder Perspectives

The determination of the essential health benefits (EHB) package (including whether more categories of care will be added to the 10 listed in Section 1302 of the Patient Protection and Affordable Care Act (ACA) or whether specific services will be classified within the existing categories), the role of state mandates in shaping the EHB package, approaches to medical necessity determinations and appeals, cost-sharing practices, and the "required elements for consideration" included in Section 1302(b)(4), are of interest to numerous stakeholders. On January 14, 2011, the committee heard five-minute presentations from 15 stakeholders, including providers, consumers, and researchers. The themes across these presentations were that in order to ultimately improve patient outcomes, the EHB package should be comprehensive, evidence-based, affordable, accommodate individual needs, and take a long-term view of the value of interventions.

PRESENTATION BY DR. R. SEAN MORRISON, NATIONAL PALLIATIVE CARE RESEARCH CENTER (NPCRC)

Dr. Morrison, the Director of NPCRC, advocated for the inclusion of palliative care[1] in the EHB package, stating that patients with serious illness have high clinical needs and therefore significantly contribute to health care costs (Morrison and Meier, 2004; Morrison et al., 2011). Under the current health insurance model, he said, the only reimbursement for palliative care is for hospice,[2] which some insurers do not cover. For those that do, to qualify for hospice reimbursement, the individual has to have a prognosis of six months or less to live, which

[1] In Dr. Morrison's words, palliative care is the medical specialty focused on preventing, treating, and relieving the pain and other debilitating effects of serious and chronic illness, including cancer, cardiac disease, respiratory disease, kidney failure, Alzheimer's, AIDS, ALS, and MS. Palliative care is interdisciplinary and patient/family centered. It is provided from the time of diagnosis and involves the relief of pain and other symptoms that cause discomfort, such as shortness of breath and unrelenting nausea. Palliative care involves extensive patient and family communication, decision making, and coordination of care. Unlike hospice care, it is not dependent on a terminal prognosis and may actually help an individual recover from illness by relieving symptoms such as pain, anxiety, or loss of appetite while undergoing sometimes difficult medical treatments or procedures, such as surgery and chemotherapy.

[2] In Dr. Morrison's words, hospice is considered the model for quality compassionate care for people facing a life-limiting illness. Hospice provides expert medical care, pain management, and emotional and spiritual support expressly tailored to the patient's needs and wishes. In most cases, care is provided in the patient's home but may also be provided in freestanding hospice centers, hospitals, nursing homes, and other long-term care facilities. In 2009, approximately 1.56 million patients (approximately 40 percent of all U.S. deaths) received services from hospice (Sutton, 2011).

Dr. Morrison called "extremely limiting." He advocated for insurers to cover palliative care "sooner than hospice" (i.e., at the time of diagnosis).

A recent study indicates that when palliative care is provided in concert with curative care at the time of diagnosis, palliative care results in better patient outcomes and survival. Lung cancer patients receiving early palliative care lived 23.3 percent longer than those who delayed palliative treatment, and median survival for "early" palliative care patients was 2.7 months longer than for those receiving standard care (Temel et al., 2010). Additionally, a 2007 study found hospice patients had a 29-day longer mean survival than patients not receiving hospice (Connor et al., 2007).

Furthermore, Dr. Morrison noted, hospice and palliative care services can lower health care costs. A study conducted at Duke University demonstrated that hospice services reduce Medicare expenses by an average of $2,309 per hospice patient while improving the quality of care provided to patients with life-limiting illness (Taylor et al., 2007). Moreover, the study found that Medicare costs would be further reduced for seven out of 10 hospice recipients if hospice was used for a longer period of time. For cancer patients, up to 233 days of hospice care decreased Medicare costs, while for non-cancer patients, up to 154 days of hospice care decreased Medicare costs. Palliative care programs in hospitals also provide "substantial savings." In a recent study comparing Medicaid beneficiaries in four New York State hospitals, provision of palliative care reduced hospital costs by $4,098 per admission for patients discharged alive and $7,563 for patients who died in the hospital. Consistent with the goals of a majority of patients and their families, palliative care recipients spent less time in intensive care, were less likely to die in intensive care units, and were more likely to receive hospice referrals than usual care patients (Morrison et al., 2011).

PRESENTATION BY MS. JINA DHILLON, NATIONAL HEALTH LAW PROGRAM (NHELP)

Ms. Dhillon, a staff attorney with NHeLP, outlined several principles for the EHB package, including flexibility to allow for the best treatment options. She advised the committee to rely on Medicaid for guidance on developing the EHB package. The standards of care for children and adolescents in Medicaid, for example, provide an array of important services, including early and periodic screening, diagnostic, and treatment services (EPSDT). NHeLP believes Medicaid EPSDT "can be an instructive model for these packages to ensure a comprehensive and robust set of services for very low-income and/or special needs children."

Ms. Dhillon suggested that the standards of care recognized by the professional academies be used to determine the scope of coverage in EHB packages. This criterion, she said, should apply both to the U.S. Department of Health and Human Services' (HHS') initial determination of the EHB package as well as to the coverage policies of insurers offering EHB packages. Relying on approved standards of care, she said, would address regional variation in implementation and prohibit plans from "providing piecemeal coverage to insured individuals where a more comprehensive scope of covered services would be more appropriate, both in saving costs and improving health." NHeLP believes that health care providers should provide information about all treatment options in accordance with the proper standards of care, based on the individual's needs, and with the overall goal of maximizing wellness. Furthermore, insurers should not be allowed to base the scope of coverage on non-clinical reasons, such as moral or religious grounds. Insurers should not be permitted to limit coverage of reproductive health services, for example.

NHeLP recognizes that in some cases, an individual may require services outside the scope of covered benefits. Therefore, NHeLP recommends that all EHB packages have a clinical exceptions process that is timely, not overly burdensome, and easily navigable by patients and providers. Medicaid can be instructive in this context; while Medicaid allows for higher cost sharing for non-preferred drugs, it also provides an exception whereby if the prescribing provider determines the preferred drug would not be as effective or if the patient would have an adverse outcome, the Medicaid enrollee can then gain access to the non-preferred drug. In some cases, Ms. Dhillon said, step therapy may be an effective strategy for providing safe, cost-effective care. However, because step therapy policies may encourage insurers rather than providers to "have the final word in treatment options," there must be "special oversight" when this policy is used. The potential negative effects of step therapy can be mitigated,

Ms. Dhillon said, by implementing a clinical exceptions process that allows "first fail" to be avoided if there is an important clinical reason for pursuing a different medical option as established by the treating provider.

Ms. Dhillon recommended that insurers directly address health disparities impacting their enrollees by offering preventive and treatment services that correspond to the health needs of specific populations. For example, if a significant number of women of childbearing age in a coverage area have diabetes, the insurer should promote reproductive health, primary care, and podiatry care, among other appropriate services. This recommendation, she said, would require insurers to conduct needs assessments of current and potential enrollees. Finally, NHeLP recommends that the process for reviewing and updating the EHB package be transparent and public, allowing time for public review and comment.

PRESENTATION BY MR. STUART SPIELMAN, AUTISM SPEAKS

Mr. Spielman, Senior Policy Advisor and Counsel for Autism Speaks, urged the committee to be mindful in making recommendations to the Secretary of congressional intent to improve the health of people with autism spectrum disorders (ASDs). The clause "including behavioral health treatment" in Section 1302(b)(1)(E) of the ACA was added by committee amendment. In the House, the amendment was offered by Representative Mike Doyle (D-PA), co-chair of the 157-member Congressional Autism Caucus, and in the Senate, the amendment was offered by Senator Robert Menendez (D-NJ). Senator Menendez's amendment, Mr. Spielman noted, was given a budget score of zero, indicating that it did not add to the cost to the health care package (U.S. Senate Committee on Finance, 2009). Additionally, Mr. Spielman referenced a letter written to the Institute of Medicine (IOM) committee by Senators Menendez, Dick Durbin (D-IL), and Robert Casey (D-PA) on the needs of individuals with autism and the importance of behavioral health care for individuals with ASDs. In a separate letter, Representative Doyle "went even further to say that it was Congress' intention" to cover applied behavioral analysis (ABA) in the EHB package. Mr. Spielman concluded that section 1302(b)(1)(E) should be understood as requiring behavioral health treatments for ASDs in the EHB benefit package.

Mr. Spielman argued that the committee should view state mandates "as informed judgments of what is needed by populations." In evaluating state mandates, Autism Speaks believes the Secretary should consider justice, cost-effectiveness, and continuity of care. Mr. Spielman noted that because underinsurance adversely affects the health of people with ASDs, Autism Speaks encourages state legislatures to enact laws mandating coverage of ASD-related benefits. Autism Speaks retained a consultant to evaluate the cost of state mandates related to autism and found that the mandates add approximately 0.42 percent to premiums (Lambright, 2011). This premium increase, Mr. Spielman argued, is offset by savings associated with increased capabilities and decreased dependence of people with ASDs. Mr. Spielman concluded that state autism laws strike a sound balance between short-term costs and long-term savings, and noted that these laws have been, and continue to be, relied upon by people with ASDs and their families.

When IOM committee member Dr. Nelson asked Mr. Spielman to describe how eligibility for an autism benefit should be determined, Mr. Spielman responded that determinations should be "person-centered." There is not a "one-size-fits-all package." An individual's needs vary depending on the severity of their symptoms; some individuals need significant amounts of care, while others need much less. In 2006, the Centers for Disease Control and Prevention (CDC) found "an average prevalence of ASDs in the United States approaching 1 percent" (CDC, 2006). Thus, Mr. Spielman said, in defining the EHB, the health needs of individuals with ASDs must be adequately addressed.

PRESENTATION BY MS. MEG BOOTH, CHILDREN'S DENTAL HEALTH PROJECT (CDHP)

As Deputy Director of CDHP, Ms. Booth advocated in favor of the inclusion of pediatric dental care in the EHB package and promoted a comprehensive, robust, affordable, and evidence-based package. She began by noting that the ACA failed to include oral health as an essential benefit necessary for individuals of all ages, but that it

did include oral health services as part of the pediatric essential benefit.[3] She added that the historic separation of medical and dental services, as well as limited efforts to address dental disease alongside other pediatric chronic conditions, challenges the implementation of a pediatric dental benefit that is inclusive of oral health care. Currently, over 90 percent of people with dental insurance receive coverage through a plan that functions separately from their medical coverage (Delta Dental, 2011). Ms. Booth noted that commercial dental coverage is typically structured as a "dental benefit plan" rather than as "dental insurance."

Prepayment vs. Risk-Sharing

To ensure affordability for employers while covering a wide range of dental services, dental benefit plans function as limited prepayment programs as opposed to risk-sharing insurance programs. These benefit plans typically provide lifetime and annually capped benefits (usually up to $2,000 annually) with potentially high out-of-pocket expenses resulting from co-payments, exclusions, frequency and age limitations, and for care delivered after an individual has reached the annual and lifetime caps. Unlike Medicaid and some Children's Health Insurance Program (CHIP) plans, these commercial benefit plans, she said, do not use a medical necessity definition as the standard for benefit determinations. This structure leaves little incentive to prevent or manage dental disease as a chronic condition.

The advantage of the existing dental benefit model, Ms. Booth pointed out, is that it allows an employer to assume a fixed and predictable premium for providing the elected level of dental coverage. The cost of the benefit is controlled by the limits placed on the scope of the benefit, which requires the enrollee to pay for care that falls outside the scope or exceeds the stated limits. The prepayment plan approach, however, fails to promote adoption of potential scientific and technologic advancements in determining covered benefits. In managing financial risk and bypassing dental necessity as the standard by which benefits are determined, commercial dental benefit plans have little incentive to modify benefit designs to respond to advances in dental science. Consequently, this model perpetuates a standard of care that should be discarded in favor of new, more effective standards that are based on individual risk and the best scientific evidence.

Fostering Prevention in the Definition of Care

Ms. Booth noted that better oral health outcomes are achieved at a lower cost if dentally necessary care is initiated in early childhood (Jokela and Pienihakken, 2003; Ramos-Gomez and Shepard, 1999; Zavras et al., 2000). Oral health risk assessments and disease management are the standards of care for determining the appropriateness and necessity of particular procedures. The American Dental Association (ADA) and the American Academy of Pediatric Dentistry (AAPD) have promoted early intervention, risk-based individualized care, and behavioral and pharmacological management of dental disease. Nonetheless, adoption of these standards by dentists "remains modest." Ms. Booth argued that the current coverage and financing of dental care continues to reward surgical treatment over pharmaco-behavioral disease management.

Models of oral health coverage provided under the EPSDT program and CHIP provide a "foundation that can be drawn upon to realign payment with a focus on prevention and disease management." These programs, she said, provide some insight for how dental necessity could be implemented in the commercial market. Commercial insurers that participate in Medicaid and CHIP typically have specialized subsidiaries that provide dental benefits. Consequently, these private insurers have experience with the administration of dental benefit design.

The Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA)[4] defined a dental benefit that was specific to the needs of children and could be used by state programs:

> coverage of dental services necessary to prevent disease and promote oral health, restore oral structures to health and function, and treat emergency conditions.

[3] Patient Protection and Affordable Care Act of 2010 as amended. Public Law 111-148 § 1302(b)(1)(J), 111th Cong., 2d sess.

[4] The Children's Health Insurance Program Reauthorization Act of 2009. Public Law 111-3, 111th Cong., 1st sess. (February 4, 2009).

CDHP recommends that the CHIPRA definition serve as a minimum standard for the essential pediatric dental benefits and suggested that the committee institute a dental necessity definition for the essential pediatric benefits that parallels a medical necessity definition and provides the opportunity to maintain parity in benefits.

CDHP aims to ensure access to affordable, comprehensive pediatric services that include a dental benefit. In designing dental benefits, Ms. Booth said, it is difficult and likely irrelevant to dictate whether a dental benefit is provided as part of a medical benefit or if it is provided through a separate limited scope dental plan. The marketplace, Ms. Booth said, "will serve as the judge in that arena." What remains critically important, however, is that regardless of the coverage structure, the system should make use of the best available research to address the unique needs of children and incentivize prevention and wellness.

PRESENTATION BY DR. ANDREW RACINE, AMERICAN ACADEMY OF PEDIATRICS

Dr. Racine, Director of General Pediatrics at the Children's Hospital at Montefiore, spoke on behalf of the American Academy of Pediatrics (AAP). He emphasized that the health care needs of infants, children, and adolescents are sufficiently distinct from those of adults and that a health care system designed for adults "will not meet the needs of America's children and should not be imposed upon them." He urged the committee to recommend comprehensive benefits modeled on the EPSDT and the recommendations contained in *Bright Futures: Guidelines for Health Supervision of Infants, Children, and Adolescents* (Hagan et al., 2008). These latter recommendations are stipulated in Section 2713 of the ACA.[5] As infants and children are in constant stages of development, their capabilities, physiology, size, cognitive abilities, judgment, and response to interventions must be continuously monitored to ensure that these changes are proceeding within an acceptable trajectory.

Medical Necessity and Evidence Development

Dr. Racine proceeded to emphasize several points from the AAP's "Policy Statement on Contractual Language for Medical Necessity for Children":

- Medically necessary services include age-appropriate prevention, diagnosis, treatment, amelioration or palliation of physical, mental, behavioral, genetic or congenital conditions, injuries, or disabilities.
- Interventions should be evidence-based but because large-scale randomized controlled trials (RCTs) are "significantly less plentiful" for children than for adults, observational studies, professional standards of care, and the consensus of pediatric experts must serve as acceptable substitutes.

Dr. Racine advised the committee that when considering coverage for experimental or investigational treatments for which no RCTs have been conducted, "individuals with the requisite knowledge of pediatric medical necessity" should be consulted to review the protocols or interventions. The "inescapable actuarial reality," he said, is that the "benefits of certain interventions in children become manifest only with a significant time lag." This time lag incentivizes plans with limited time horizons to minimize the importance of these interventions. Such incentives, he said, place children at a distinct disadvantage when coverage decisions are being made.

When committee member Dr. Selby asked for additional details about the evidence-base in pediatrics and whether the application of observational data has interfered with coverage for individual children, Dr. Racine responded that observational studies are often—and indeed have to be—used because few RCTs exist. However, Dr. Racine noted that that while there is a lot of off-label use of medications for children, most health plans will not cover these uses because the use is not supported by a RCT. Furthermore, he said, health plans have denied habilitative services on the grounds that occupational therapy for children with cerebral palsy is not supported by evidence.

[5] Section 1001 of the Affordable Care Act, amending the Public Health Service Act by inserting Section 2713 outlines specific preventive services each health plan must provide without any cost sharing, including specific services for children, like screenings and immunizations supported by CDC and HRSA.

Full Range of Care

Children are uniquely dependent on caregivers to detect medical problems, provide access to health care, translate the nature of their symptoms to clinicians, receive recommendations for care, and arrange for and monitor ongoing treatments. As most children are healthy, the epidemiology of disease is different than in the adult population. Nevertheless, Dr. Racine said, an "important segment of children" suffer from chronic conditions that affect their development and require specific attention to generating, maintaining, and restoring age appropriate functioning. He also noted that children differ from adults in that the economic, ethnic, and racial demographics of the U.S. pediatric population put children at risk of adverse outcomes due to existing health care disparities.

To account for these differences between children and adults, Dr. Racine argued that EHB for infants, children, and adolescents must include not only preventive care, but "the full range of diagnostic, therapeutic, and ongoing counseling and monitoring" for both healthy children and children with developmental disorders, chronic conditions, and behavioral, emotional, and learning disabilities. Dr. Racine concluded by advising the committee that the mechanisms created to update the EHB package should include input from physicians. Furthermore, he said, the EHB package should be periodically reviewed to ensure that it appropriately reflects ongoing changes in clinical science.

PRESENTATION BY DR. GERALD HARMON, COUNCIL ON MEDICAL SERVICE, AMERICAN MEDICAL ASSOCIATION (AMA)

Dr. Harmon began by emphasizing that AMA policy is that the EHB should maximize patient choice of health plans and benefit packages and that the AMA supports the use of health savings accounts (HSAs). The AMA, he noted, believes that the interpretation of "essential" in the context of an EHB package should align with existing federal guidelines regarding types of health insurance coverage. Existing regulations, such as those governing the operation of the Federal Employees Health Benefit Program (FEHBP), for instance, reflect the reality that patients define "essential" based on individual health care needs and budgetary restrictions. The AMA believes that health insurance should provide coverage for hospital care, surgical and medical care, and catastrophic medical expenses, as defined in the tax code.[6] Section 9832 of the tax code refers to "medical care" as care for the

> diagnosis, cure, mitigation, treatment, or prevention of disease, or for the purpose of affecting any structure or function of the body and for transportation essential to medical care.

Secondly, AMA supports using the existing FEHBP as a reference "when considering if a given plan" would provide meaningful coverage. Dr. Harmon noted that all FEHBP plans cover basic hospital, physician, surgical and emergency care, even though the program does not require a standard benefit package. FEHBP follows existing evidence-based guidelines for preventive care for children and adults, and plans are required to cover additional benefits including child immunizations, prescription drugs, mental health services (with parity to medical care coverage), and a catastrophic limit for out-of-pocket (OOP) costs. It is important to note, he said, that even with these requirements, FEHBP "is able to offer high-deductible health plans coupled with HSAs, as well as consumer-driven health plans."

Third, the AMA "firmly believes" that the development of an EHB package should not "undercut the vital role in the health insurance marketplace of high-deductible health insurance plans issued to individuals and families in conjunction with HSAs." Offering a range of health plan choices, including high-deductible health plans (HDHPs) coupled with HSAs, will enable patients to select health plans that meet their health care needs and budgetary realities.

Medical Necessity

In response to the committee's inquiry about how insurers apply medical necessity, Dr. Harmon provided the AMA definition of medical necessity:

[6] U.S. Code, Title 26 § 213.

> Health care services or products that a prudent physician would provide to a patient for the purpose of preventing, diagnosing or treating an illness, injury, disease or its symptoms in a manner that is: (a) in accordance with generally accepted standards of medical practice; (b) clinically appropriate in terms of type, frequency, extent, site, and duration; and (c) not primarily for the economic benefit of the health plans and purchasers or for the convenience of the patient, treating physician, or other health care provider.

He noted that the "prudent physician" standard of medical necessity ensures that physicians are able to use their expertise and to exercise discretion, consistent with good medical care, in determining the medical necessity of care provided to individual patients.

Furthermore, Dr. Harmon argued that the "prudent physician" standard will only be strengthened by results of comparative effectiveness research (CER). Such research, he said, has the potential to have a "profoundly positive impact on the quality of the information available to physicians and patients" by fostering the delivery of patient-centered care and enhancing physician clinical decision making. Dr. Harmon argued that strong physician-patient relationships allow physicians and patients to jointly participate in making value-based health care decisions. At the point of decision making, physicians should have access to the best available evidence. Clinical information about health conditions, treatment options, and potential outcomes can then be discussed with patients.

The AMA has historically opposed definitions of medical necessity that emphasize cost and resource utilization above quality and clinical effectiveness. Such definitions of medical necessity, Dr. Harmon argued, interfere with the patient-physician relationship and prevent patients from getting needed medical care. To determine medical necessity, health plans should develop formal protocols that distinguish between when in-house medical expertise is sufficient and when outside consultation is necessary. Medical necessity determination processes should include an opportunity for the treating physician to provide additional evidence before a final coverage decision is made. Additionally, when health plans deny coverage for reasons of medical necessity, the plan needs to facilitate the expeditious handling of requests for reconsideration and appeal.

Required Elements for Consideration

Rather than striving for an "appropriate balance" among the 10 categories of care included in the ACA, Dr. Harmon urged the committee "that the goal instead should be to ensure parity in terms of access and coverage among the ten categories listed." In ensuring parity among these categories, factors such as OOP costs and benefit limits must be considered. A "prudent physician" standard could be applied, he said, as physicians have the "unique ability" to help ensure that patients "get the right care, at the right time, in the right place."

In deciding what is medically necessary, age and disability have to be taken into consideration by the "prudent physician," Dr. Harmon stated. EHB, like any other health insurance benefit, need to be age-appropriate. Individuals within each age group should have a wide variety of coverage options from which to choose, including coverage options more comprehensive than the EHB package. The EPSDT program can be used as a model to account for the health care needs of diverse segments of the population. Under EPSDT, if a medical treatment or service will help a child, the treatment can be authorized by the Medicaid medical director even when the state Medicaid program does not specifically cover the treatment.

When committee member Dr. Michael Chernew asked Dr. Harmon how to deal with situations in which a service is covered, but not necessarily for every patient, Dr. Harmon reiterated the importance of the "prudent physician" standard. It is difficult, he said, "to micromanage each individual patient that has his or her own requirements," but standards (including those based on CER) should be established. Dr. Harmon noted that individuals with congenital or acquired disabilities should have access to appropriate and affordable medical care throughout their lives. Furthermore, benefits deemed to be essential for individuals with disabilities may need to be more comprehensive than those for individuals without disabilities. High-risk pools, Dr. Harmon suggested, could be used to provide affordable care for individuals with additional health care needs. Additionally, he said, the AMA supports the coverage of care, services, treatments, and interventions uniquely for women. Furthermore, the AMA believes an appeals process should be established in every state (through the state department of insurance or other state agency) to ensure fair and non-discriminatory practices in the application of the EHB package.

Updating the EHB Package

To assess whether and how enrollees are facing difficulty accessing needed services for reasons of cost or coverage, Dr. Harmon suggested that HHS establish surveys, a hotline, and a website to receive information from patients, physicians, hospitals, and other stakeholders. Dr. Harmon also advocated for the inclusion of patient groups (e.g., AARP and Families USA) and physician organizations when assessing the experiences of enrollees with the EHB package. To update the EHB package, Dr. Harmon said HHS should convene an advisory committee that includes practicing physicians and patient representatives.

PRESENTATION BY DR. ROBERT MURPHY, AMERICAN SOCIETY OF PLASTIC SURGEONS (ASPS)

Dr. Murphy, Vice President of Health Policy and Advocacy for ASPS, insisted that Section 1302 needs further clarification regarding medical and surgical care. For instance, ambulatory patient services, he said, should include surgical care (e.g., anesthesia, minimally invasive and noninvasive procedures). He proceeded to argue that the EHB package should cover reconstructive surgery when the surgery meets the AMA definition of reconstructive surgery:

> surgery performed on abnormal structures of the body, caused by congenital defects, developmental abnormalities, trauma, infection, tumors or disease. It is generally performed to improve function, but may also be done to approximate a normal appearance. (ASPS, 2005)

This definition was included in the Children's Access to Reconstructive Evaluation and Surgery (CARES) Act of 2009,[7] which distinguished between cosmetic and reconstructive surgery (using the AMA definition) and specifically excluded cosmetic surgery (defined as surgery performed to reshape normal structures of the body to improve appearance or self-esteem).

Denials of Care on an Insurer-Deemed Cosmetic Basis

According to the March of Dimes, 3 percent of babies born annually (120,000) suffer from birth defects[8] and approximately 40,000 require reconstructive surgery (ASPS, 2009). Although surgeons are able to correct many of these problems, Dr. Murphy noted that an increasing number of insurers deny coverage by labeling the procedures "cosmetic" or "non-functional" in nature. An ASPS survey found that 54 percent of respondents had pediatric patients who had been denied coverage or who experienced "significant and deleterious obstacles in obtaining approval for coverage" of surgical procedures (ASPS, 2009). Furthermore, although insurers may provide coverage for the initial procedure, Dr. Murphy said, they "regularly resist coverage of the later stage procedures," claiming the procedures are cosmetic and not medically necessary. He argued that "too many American families are experiencing delays or denials to health care that would prevent long-term physical and psychological injuries." He reiterated that the procedures used to treat these children are, by definition, reconstructive, and should be covered by insurance. When committee member Dr. Santa asked which services should be covered, Dr. Murphy indicated the need for consumer involvement in these decisions and that the ASPS believes decisions should be based on the strength of evidence supporting a procedure.

[7] Children's Access to Reconstructive Evaluation and Surgery (CARES) Act of 2009, HR 1339, 1st sess. (March 5, 2009).

[8] Defined as an abnormality of structure, function, or body metabolism present at birth that results in physical or mental disabilities or is fatal (e.g., cleft lip, cleft palate, skin lesions, vascular anomalies, malformations of the ear, hand, or foot, and other more profound craniofacial deformities).

PRESENTATION BY MS. LINDA FISHMAN, AMERICAN HOSPITAL ASSOCIATION (AHA)

Ms. Fishman, Vice President of Public Policy Analysis and Development for the AHA, proposed that the EHB package cover a broad range of services including medical, psychiatric, rehabilitative, dental, vision, preventive and hospice services, as well as pharmaceuticals. The package, she said, should be patient-centered, accessible, and adhere to accepted professional guidelines. She suggested a three-pronged framework for assessing which benefits to include:

- Are the benefits responsive to individual needs?
- Do the benefits take affordability into account?
- Are the benefits easily understood and transparent?

Furthermore, she argued that any limits placed on the EHB package be "grounded in clinical best practices." Such limits, she said, could focus on services that are marginally effective and could change as underlying scientific evidence or CER informs clinical best practices. However, "particular types of services should not be eliminated wholesale." Rather, limits could include the number or frequency of diagnostic tests or procedures. Ms. Fishman concluded by arguing that the lack of a consistent and recognized standard for essential benefits "allows insurers to control not only coverage decisions but also treatment decisions, sometimes overriding clinical standards and the patient's needs." The rules and decision processes that govern EHB and medical necessity should, she said, be transparent so that enrollees understand in advance the limitations of their coverage.

PRESENTATION BY MR. JOHN FALARDEAU, AMERICAN CHIROPRACTIC ASSOCIATION

Mr. Falardeau, Vice President of Government Relations for the American Chiropractic Association, outlined principles for the committee's consideration. Care that increases health and reduces health care costs must be considered in designing the EHB package, he said. To achieve cost reductions, HHS should focus on covering "more conservative, low-risk, outpatient services that emphasize partnering with patients." More invasive, high-risk, inpatient procedures "should be used sparingly" and only if they have "a very strong evidence base of comparative clinical effectiveness and relative safety." Ensuring transparency and creating greater patient involvement are two overarching goals of the ACA, he noted. Those same principles should be applied to the EHB package. Mr. Falardeau advised the committee to include all benefits that are mandated by at least 25 states in the EHB.

Mr. Falardeau argued that "the [committee's] top priority should be to ensure a complete" EHB package, as opposed to having "an equal number of services in each of the 10 categories." He also cautioned the committee to "guard against the possibility" of the EHB being denied against the wishes of patients based on age, expected length of life, and other considerations. To "protect" these benefits, he said, determinations cannot solely be left to individual or collective health plans. If an EHB is denied, patients should have the right to an independent, third-party review of the claim. This process, he said, could be similar to the regulations that require all new group plans to have a straightforward and independent appeals process.[9]

Certification of Coverage

Mr. Falardeau advised HHS to develop a template certificate of coverage or summary plan description for health insurers. This could be similar, he said, to Blue Cross Blue Shield's FEHBP brochure and could list the 10 categories of services outlined in the ACA with the EHB mandated by HHS outlined beneath each category. By requiring plans to use a template certificate of coverage, HHS and health insurance exchanges could more easily determine if the benefits offered by the plan meet the requirements of the law. Additionally, the template would be helpful to consumers as they compare coverage and would ensure plans are clearly communicating to patients that the services listed under "essential benefits" must be made available to them (provided the patient is receiv-

[9] Patient Protection and Affordable Care Act of 2010 as amended. Public Law 111-148 § 10101(g) and (h), amending the Public Health Service Act by inserting §2719, 111th Cong., 2d sess.

ing the service from a licensed health care provider acting within their scope of practice), without discriminatory restrictions or limitations.

PRESENTATION BY DR. ARNOLD COHEN, AMERICAN CONGRESS OF OBSTETRICIANS AND GYNECOLOGISTS (ACOG)

Dr. Cohen, Chairman of the Department of Obstetrics and Gynecology at Albert Einstein Medical Center, spoke on behalf of ACOG. He began by asking the committee to look to ACOG's clinical and practice guidelines when determining the EHB related to women's health. He also remarked that defining the EHB as specifically as possible "is the surest way to protect our patients against potential conflict or debate regarding medical necessity." Every pregnant woman should have the ability to determine for herself whether first-trimester ultrasounds or screening for Down syndrome, for instance, are appropriate. Plans should not decide whether a specific screening is "right or wrong, or medically necessary." Furthermore, as the ACA guarantees direct access to obstetricians/gynecologists (OB/GYNs), pregnant women should not have to rely on referrals for pregnancy-related services such as maternal/fetal medicine consultations or ultrasounds. Dr. Cohen also argued that plans should not limit contraceptive choices. Currently, he said, some plans cover only one type of contraceptive pill or intrauterine device (IUD), despite that there are many alternatives available.

Medical Necessity

The definition of medical necessity, he said, should ensure quality of care while safeguarding insurers from unexpected circumstances. He asked the committee to adopt the definition of medical necessity developed by the AMA, but advised that some terms in the definition need further clarification. For instance, a physician practice should be deemed "in accordance with generally accepted standards" if s/he adheres to the guidelines developed and adopted by the practice's medical specialty. For example, an OB/GYN would be considered a prudent physician if s/he followed ACOG guidelines, such as when non-medically indicated elective inductions of labor before 39 weeks of gestation are and are not appropriate.

The definition of medical necessity, Dr. Cohen argued, must allow for medically appropriate off-label use of FDA-approved drugs and devices, a common practice in OB/GYN. For example, he noted that although the FDA does not approve the use of terbutaline to delay delivery for the purposes of enhancing fetal maturation, its use for this purpose is accepted medical practice. Similarly, misoprostol, which is FDA approved for use in peptic ulcer disease, is not approved to treat incomplete or missed abortions. The drug, though, is commonly used by OB/GYNs for this purpose.

Furthermore, the definition of medical necessity should allow for coverage of preventive interventions and counseling services that are often not covered (e.g., nutrition counseling, weight-loss management, smoking cessation, and counseling for postpartum depression). While these services are supported by varying levels of scientific evidence, ACOG has reviewed this evidence to develop guidelines that can serve as the standard for coverage, he said. Dr. Cohen closed by stating that ACOG believes medical necessity decisions should be made through peer-review processes that include expert specialists and sub-specialists.

PRESENTATION BY MR. THOMAS SELLERS, NATIONAL COALITION FOR CANCER SURVIVORSHIP (NCCS)

Mr. Sellers, President and CEO of the NCCS, presented his organization's recommendations for the EHB related to cancer care. The committee, he urged, should recognize the multidisciplinary nature and complexity of cancer care, rapid changes in evidence-based care as a result of clinical investigation, the evolution of cancer as a chronic disease, and the importance of facilitating patient decision making. Well-planned and well-coordinated cancer care, he said, is in the best interest of patients and is "best for the health care system because it ensures the appropriate utilization of the health care resources." NCCS recommends coverage of cancer care planning

and coordination, coverage of off-label uses for cancer therapies, and coverage of routine patient care costs for patients enrolled in clinical trials.

For the purposes of defining EHB, cancer should be considered a chronic disease so that cancer patients can access care planning and coordination services. Specific elements of planning and coordination services and the frequency of these services should be included. Additionally, Mr. Sellers noted that "the frequency of access to cancer care planning services should be defined to ensure that the service is available across the continuum of care." Specifically, access to the service should be available for treatment planning, treatment plan modifications, creation and communication of a summary of treatment, and follow-up survivorship care. Greater specificity, Mr. Sellers said, is necessary to ensure that cancer care plans adequately define all the elements of active treatment, symptom management, and survivorship care, and encourage care coordination among all providers across all sites of care. Including such services as a part of the EHB package is, Mr. Sellers said, "an important investment in quality care, and it goes a long way towards implementing the recommendations of the Institute of Medicine's 2006 report, *From Cancer Patient to Cancer Survivor: Lost in Transition*" (IOM, 2006a).

Off-Label Drug Use

Mr. Sellers reiterated that "it is critically important" that the definition of EHB include access to off-label uses of cancer drugs. Between 50 and 75 percent of all uses of cancer drugs are off-label use, according to the National Comprehensive Cancer Network (ASCO, 2005). Although cancer research attempts to rapidly define supplemental uses of drugs approved by the FDA, this research does not necessarily or rapidly lead to changes in product labeling. To ensure patient access to evidence-based therapies, plans should not be permitted to prohibit payment for off-label uses of cancer drugs.

Medicare statutes, Mr. Sellers said, balance the need to ensure access to off-label use with reliance on evidence. According to Medicare statutes, off-label use of a cancer drug must be covered if the use is listed in a CMS-approved medical compendium. Furthermore, off-label use may be covered if the use is supported by peer reviewed medical literature.[10] These standards, Mr. Sellers said, have "worked well and have generally been followed by private third-party payers." To protect access to quality cancer care and all appropriate treatment options, NCCS recommends the definition of off-label use coverage standards in the EHB package.

Clinical Trials

The ACA includes a provision requiring the coverage of routine patient care costs for patients enrolled in clinical trials for cancer or other life-threatening diseases or conditions.[11] NCCS, Mr. Sellers said, recommends that the EHB package clearly reflect this standard and that HHS consider expanding coverage to routine patient care costs for individuals enrolled in all clinical trials (i.e., not just clinical trials related to cancer or other life-threatening diseases). Mr. Sellers concluded by noting that cancer advocates "worked for many years to establish a standard for coverage of cancer trials through the Medicare program" and that when CMS established a policy of coverage of routine patient care costs in clinical trials, the agency made the policy applicable to trials in all diseases (CMS, 2007). This Medicare policy, he said, has "yielded significant benefits for individual patients and for the health care system" because patients are permitted to enroll in trials without fear that their routine costs will be denied.

PRESENTATION BY MR. TROY ZIMMERMAN, NATIONAL KIDNEY FOUNDATION (NKF)

Mr. Zimmerman, Vice President for Government Relations at the NKF, noted that medical coverage is typically determined by what is reasonable and necessary, a "vague definition" that can inhibit innovation and patient choice. For example, Medicare's dialysis reimbursement policy, which reimburses three treatments weekly, has

[10] Social Security Act, 42 U.S.C. 1395w-102§ 1860D-2(e).

[11] Patient Protection and Affordable Care Act of 2010 as amended. Public Law 111-148 § 1201, amending the Public Health Service Act by inserting § 2709 as added by § 10103(c), 111th Cong., 2d sess.

remained virtually unchanged over 40 years. Such a rigid policy, he said, inhibits utilization of new modalities. For example, despite the convenience of home daily dialysis, its use has remained low over the past few decades. Ninety percent of dialysis patients receive traditional in-center dialysis.

The NKF, Mr. Zimmerman said, believes dialysis therapy should "best fit the needs of the individual patient." Home therapies may be more convenient for patients in the workforce, and they eliminate transportation challenges. Furthermore, a recent study demonstrated that frequent dialysis consisting of six weekly hemodialysis treatments improved left ventricular mass and self-reported health (The FHN Trial Group, 2010). As a result of this finding and others, Mr. Zimmerman urged HHS to include all dialysis modalities in the EHB package.

Similarly, coverage limitations may be a barrier to kidney transplantation, which is often the most cost-effective alternative for candidates with kidney failure. Private insurance will often only cover a prospective living organ donor's medical tests if that individual becomes a donor. In many instances, however, a patient with kidney failure must go through several prospective living organ donors before one is identified as appropriate. As the gap between the number of individuals on the kidney waiting list and the number of available organs continues to widen, living donation is an increasingly important mode of transplantation.

Mr. Zimmerman noted that the NKF argues against limits on specific benefits such as limits on the modality or number of dialysis sessions for a patient, or limits on access to repeated transplants for failed grafts. Additionally, to ensure the best outcomes for individual transplant recipients, the EHB package, he said, should cover the necessary immunosuppressive drugs, laboratory tests, and post-transplant examinations.

Prevention in High-Risk Populations

An individual with advanced chronic kidney disease is likely to die of complications prior to needing renal replacement therapy. Stage 4 kidney patients, for example, are more likely to die of congestive heart failure than to progress to dialysis (Foley et al., 2005; Keith et al., 2004). The 2010 U.S. Renal Data System (USRDS) Annual Report notes that because a patient with chronic kidney disease is more likely to have a cardiovascular event and die than to reach end-stage renal disease, it is imperative to identify chronic kidney disease among individuals who have been diagnosed with diabetes and/or hypertension, the two leading causes of chronic kidney disease and end-stage renal failure. This identification would allow patients and their providers to monitor risk factors for cardiovascular events and address the progression of kidney disease (USRDS, 2010). Mr. Zimmerman noted that group health plan enrollees are less likely to see a nephrologist prior to end-stage kidney failure than their Medicare counterparts (USRDS, 2010).[12]

In conclusion, Mr. Zimmerman stated that virtually all end-stage renal disease patients, regardless of age, are covered by Medicare 30 months after the start of their kidney-replacement therapy or, in the case of those who do not have group health insurance, three months after the start of kidney-replacement therapy. Therefore, he said, insurers may be reluctant to cover preventive and early detection for chronic kidney disease, expending resources on interventions only to see those policyholders move to another insurer.

PRESENTATION BY MR. RICHARD SMITH, PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA (PhRMA)

Mr. Smith, Senior Vice President for Policy and Research at PhRMA, noted that his organization represents the nation's biotechnology and pharmaceutical research companies and believes the definition of EHB plays "an important role in assuring" support for needed treatments across the benefit categories, regardless of the treatment setting or mode. Furthermore, the design of the EHB package, he said, plays a role in providing adequate financial protection for all patients, "whether they live with a chronic condition or have acute health care needs."

[12] The data reported here have been supplied by the U.S. Renal Data System (USRDS). The interpretation and reporting of these data are the responsibility of the author(s) and in no way should be seen as an official policy or interpretation of the U.S. government.

Design Principles

The committee, Mr. Smith argued, should consider four principles:

- Coverage should provide access to needed medical treatment across benefit categories, regardless of the setting or mode of treatment.
- Risks should be spread broadly rather than concentrated on patients with high costs.
- The needs of patients with chronic as well as acute conditions should be recognized.
- Providers and patients should have choices among therapeutic options, and new treatments should be incorporated into coverage.

Provider and patient choice is essential to ensuring that the EHB meet patients' diverse health care needs. Insurers should have flexibility to manage costs but must provide patients and providers with a "meaningful choice of treatment options," including brand medicines and generic drugs. Employer-sponsored insurance typically features a tiered cost-sharing formula that includes broad coverage for preferred-brand drugs on the second tier and uses various management tools. These tools, he noted, must allow for meaningful access to needed care and focus on the full range of benefits rather than simply on costs.

Cost-Sharing Barriers

Extensive evidence shows that high cost sharing discourages patients from taking needed medications (DiMatteo, 2004) and plays a role in what Mr. Smith called "the non-adherence problem." This problem is estimated to generate $100 to $300 billion in higher health care costs and lost productivity annually (Shorter, 1993). Because the impact of high cost sharing is most pronounced for low-income patients, cost sharing has been cited as a contributing factor to increasing health disparities (Chernew et al., 2008). In recognition of the problems created by high cost sharing, Mr. Smith said, employers have begun to introduce innovative programs that reduce or eliminate cost sharing for medicines. These programs improve adherence, enhance productivity, and reduce overall costs (Freudenheim, 2007; Fuhrmans, 2007).

Mr. Smith urged the committee "to focus on the statutory standard," and ensure benefits are not "unduly weighted toward any one category, given the rapid changes in the patterns of care and the important role that oral, injected, and infused medicines and vaccines play in effective prevention and management of conditions." The protection against high OOP costs is one of the principal functions of insurance—to broadly pool high- and low-risk individuals in order to provide financial protection against catastrophic costs. "Simply put," he said, "severely and/or chronically ill patients should not bear a disproportionately high share of the cost of care." Additionally, he said, increasing cost sharing transfers a financial burden from the health plan to the patient and does little to reduce overall health care spending (Goldman et al., 2006). Some tiered cost-sharing designs shift costs to sick patients rather than creating meaningful incentives for high-quality care. Some Medicare Part D plans, for example, have created a specialty tier that typically features high cost sharing for medicines to treat cancer, HIV/AIDS, multiple sclerosis, and rheumatoid arthritis. PhRMA urges the IOM and HHS to carefully consider how to set guidelines consistent with the goals of ACA. These goals, he said, include ensuring that policies do not unfairly shift burdens to the sickest patients and create barriers to needed care.

Historically, most insurance was intended to provide protection for acute needs. Today, however, many treatments allow for effective control of chronic conditions that have previously had few management options. The needs of patients with chronic conditions, Mr. Smith said, "require focused attention." Quality health insurance should reflect these needs and provide adequate protection to all patients, including those whose costs are spread out over time rather than concentrated in a single episode of care.

Mr. Smith closed by noting that access to new treatments is important to improving quality of life, reducing costs, and preventing, treating, and potentially curing serious and chronic conditions. Therefore, standards for formulary design and medical management should recognize the development of new treatments and therapies.

For example, some of the rules for implementing Medicare Part D recognized new therapies by building on best practice formulary designs and medical management tools used in the private sector.

PRESENTATION BY MR. BRIAN GALLAGHER, AMERICAN PHARMACISTS ASSOCIATION

Mr. Gallagher, Senior Vice President for Government Affairs at the American Pharmacist Association (APhA), stated that his organization represents over 62,000 pharmacists in a variety of settings. He began by defining medication therapy management (MTM) as a distinct service or group of services that optimizes therapeutic outcomes for individual patients (Bluml, 2005). The focus of MTM, he said, is providing team-based, individualized care to the patient. A foundational MTM service delivery model has specific "core elements" (i.e., medication therapy review, personalized medication record, medication-related action plan, intervention and referral, documentation, and follow-up) (APhA and NACDS, 2008).[13] The goals of MTM are to improve collaboration among pharmacists, physicians, and other health professionals; enhance communication between patients and the health care team; and empower patients to optimize medication use for improved health care outcomes.

Mr. Gallagher noted that because services included in the definition of MTM are also included in the calculation of the medical loss ratio, these services should be included as an essential health benefit. Because MTM can optimize the use of medications and decrease overall health care costs by preventing adverse events, reducing hospital admissions, readmissions, and medical errors, Congress, he said, referenced MTM in Section 3503 of the ACA,[14] and is a required benefit for targeted beneficiaries through Medicare Part D.[15] Furthermore, Mr. Gallagher emphasized that "inappropriate use of medications costs an estimated $177 billion" (Ernst and Grizzle, 2001) and results in over 1.5 million preventable medication-related adverse events annually (IOM, 2006b). The Public Health Service has successfully used MTM and pharmacist intervention since the 1960s and numerous studies have documented the cost benefits of MTM to patients and health care systems (Chisholm-Burnes et al., 2010; Moore and Abramek, 1992; Perez et al., 2008; Schumock et al., 2003).

APhA developed the definition and core elements service model for MTM by convening diverse stakeholder groups (including physicians and other health care providers, policy makers, health plans, and quality organizations) and continues the dialogue about MTM services with these stakeholders. While all patients using prescription, nonprescription, herbal and other dietary supplements could potentially benefit from MTM, patients in transitions of care, patients who have changed medication regimens, and patients who have multiple medications, multiple chronic conditions, or a history of non-adherence are most likely to benefit. Patients who are empowered to take an active role in medication self-management have improved health as a result of a better functioning health care team. Mr. Gallagher noted that medication use can be optimized by removing barriers such as co-pays and deductibles (Bunting and Cranor, 2006). While medication spending may actually increase under MTM, overall medical costs for hospitalizations can be reduced (Bunting and Cranor, 2006; Fera et al., 2009).

Mr. Gallagher concluded by reiterating that medications are central to managing many disease states. "If the system is going to spend huge percentages of money for medications, we should be making sure that those medications are used optimally." He encouraged the committee to recommend that the EHB package include a mechanism to optimize medication use through MTM services.

PRESENTATION BY BRUCE WOLFE, OBESITY CARE CONTINUUM (OCC)

Dr. Wolfe, President of the American Society for Metabolic and Bariatric Surgery (ASMBS), spoke on behalf of the OCC. This coalition is comprised of the Obesity Action Coalition, American Dietetic Association, Obesity Society, and ASMBS, and represents the interests of individuals affected by overweight and obesity and the health care professionals and researchers who care and develop treatments for this growing population. The Congressional

[13] A visual representation of MTM is presented in Appendix E of *Medication therapy management in pharmacy practice: Core elements of an MTM service model,* available at: http://www.accp.com/docs/positions/misc/CoreElements.pdf (accessed August 18, 2011).

[14] Patient Protection and Affordable Care Act of 2010 as amended. Public Law 111-148 § 3503, amending Title IX of the Public Health Service Act by inserting § 935, 111th Cong., 2d sess.

[15] Medicare Prescription Drug, Improvement, and Modernization Act of 2003, § 1860D-4 (c)(2).

Budget Office estimated that over the past 20 years, the impact of obesity on health care expenditures has doubled and that obese individuals have at least 20 percent higher costs than lean subjects (CBO, 2010).

Obesity is a disease with multiple co-morbidities. Behavior modification and surgery, Dr. Wolfe said, are effective treatments for obesity and the prevention of obesity-related events, including death due to cardiovascular disease, cancer, and diabetes (Adams et al., 2007; Knowler et al., 2002; Sjostrom et al., 2007). Epidemiologic studies, he noted, demonstrate that mortality sharply increases when an individual's body mass index (BMI) is above 30, the threshold for diagnosing obesity (Calle et al., 1999; Prospective Studies Collaboration, 2009). As 5 percent of the U.S. population has a BMI exceeding 40, the need to prevent and treat obesity is "pressing" (Sturm, 2007). Co-morbidity data from the NIH Consortium on Bariatric Surgery (LABS) show that 35 percent of obese individuals have diabetes and more than 50 percent have sleep apnea and hypertension (LABS Consortium, 2008). Despite this high cardiovascular risk, bariatric surgery, Dr. Wolfe said, presents a "window of opportunity" (LABS Consortium, 2008). However, access to obesity prevention and treatment is severely limited.

Behavioral Modification

Obesity treatment is clearly recognized as an important component of comprehensive health care services. The U.S. Preventive Services Task Force recommends that clinicians screen adult patients for obesity and offer intensive counseling and behavioral interventions to promote sustained weight loss for obese adults. Similarly, the Oregon Medicaid prioritized list of health services defines obesity treatment as "intensive nutritional/physical activity counseling and behavioral interventions" and lists it as the eighth highest priority (out of 679 conditions). Dr. Wolfe noted that bariatric surgery is one treatment for certain obese individuals with Type II diabetes, which ranks as thirty-third priority (OHSC, 2010). Intense behavior modification can result in a modest but definite sustained weight loss of 5 percent after four years (Look AHEAD Research Group, 2010). This weight loss was associated with a reduction in the need for diabetes and hypertension medication and improved control of these chronic conditions.

Bariatric Surgery

Weight loss following bariatric surgery is substantially greater than the weight loss associated with usual care (Sjostrom et al., 2007). Dr. Wolfe argued that bariatric surgery is safe, citing a mortality rate of 0.3 percent and a complication rate of 4.3 percent among all patients undergoing laparoscopic gastric bypass, open surgery, and laparoscopic adjustable gastric banding (LABS, 2009). Using data from a multi-year study conducted in Sweden, Dr. Wolfe showed that after 13 years the survival gap between patients who had bariatric surgery and those who received "the customary treatment for obesity at their centers of registration" widened (Sjostrom et al., 2007). This gap occurred, Dr. Wolfe said, as the result of remission of diabetes, hypertension, hyperlipidemia, sleep apnea, and a reduction in the incidence of cancer (Buchwald et al., 2004; Sjostrom et al., 2007).

Despite these demonstrated benefits of weight loss, intensive weight loss counseling is infrequently reimbursed by insurers (Tsai et al., 2006), and less than 2 percent of eligible patients undergo bariatric surgery annually (Kofman and Miller, 2010; Livingston, 2010). Dr. Wolfe argued that this lack of uptake results from a lack of knowledge of the benefits of bariatric surgery and a lack of financial coverage (Lee et al., 2010). Insurers often do not cover obesity treatment, he said, because (1) of the delay on return of investment of 2 years or more, resulting from the upfront cost of bariatric surgery and subsequent reduced health care costs associated with improved outcomes (Crémieux et al., 2008), (2) employers reject obesity treatment riders (Blackstone, 2010), and (3) there is a "bias against obesity" due to the perception that obesity results from self-induced inappropriate lifestyle, which can and should be corrected by individual lifestyle changes (Puhl and Heuer, 2009).

When committee member Mr. Schaeffer asked about the costs of laparoscopic gastric bypass, open surgery, and laparoscopic adjustable gastric banding, Dr. Wolfe noted that while the costs and complications vary, laparoscopic bypass costs approximately $17,000 and open gastric bypass costs approximately $26,000, excluding complications (Crémieux et al., 2008). Open surgery, he said, is only done on patients who have complex problems from previous surgery or hernias (approximately 10 percent of the population). Laparoscopic gastric banding, on the

other hand, is generally done on a same-day outpatient basis and costs between $10,000 and $15,000. Dr. Wolfe concluded that reimbursement for the treatment of obesity requires special consideration due to the remarkable health benefits achieved.

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10

Two Private-Sector Approaches to Benefit Coverage and Design

To further inform its understanding of how insurers reach decisions on covering benefits, the Institute of Medicine (IOM) committee held a second public workshop, starting off with presentations by a health insurer, WellPoint, and an integrated delivery system with both insurance and delivery components, Kaiser Permanente. Samuel Nussbaum, Executive Vice President, Clinical Health Policy and Chief Medical Officer at WellPoint, started off by describing that company's approach to building health care improvement into its choice of evidence-based benefits, clinical policies, modes of delivery, and incentives. He stressed that deciding the covered benefits is just the first step, followed by benefit design choices and benefit administration. Sharon Levine, the Associate Executive Medical Director of The Permanente Medical Group, reviewed its framework for deciding benefits, how market factors influence those choices, Kaiser's environment of examined practice, and variations across plans (e.g., choices in contractual exclusions, requirements of state mandates). These private-sector approaches are illustrative of many steps in defining a benefit package and its implementation.

PRESENTATION BY DR. SAMUEL NUSSBAUM, WELLPOINT, INC.

Dr. Nussbaum began by describing the complementary factors that plans must consider when defining benefits. First, as 5 percent of WellPoint's 34 million members drive 54 percent of its costs, WellPoint aims to design benefits in a way that promotes health and wellness (Nussbaum, 2011). "Baking health improvement into the benefit package," he said, will improve health and lower cost. Second, because unsustainable health care costs "actually threaten what we can achieve in terms of technology advances and scientific innovation," WellPoint's benefit design aims to balance affordability with value, quality, and effectiveness. WellPoint invests in treatments that have been scientifically proven, and the company works to reduce the use of inappropriate and ineffective treatments. The company monitors improvement in 40 quality measures across domains of screening and prevention, care management, clinical outcomes, and patient safety, and also compares health status achievement among its members.

Dr. Nussbaum cited WellPoint's process for assessing medical technology as an example of how WellPoint seeks to improve health care and lower costs while building on a foundation of proven clinical science and outcomes. The health plan makes evidence-based decisions about whether and when benefits should be covered after considering emerging science, expert clinical opinions, and reviews of the medical literature. As described in Figure 10-1, committees of clinical experts on specific subjects such as hematology, oncology, and behavioral health guide these decisions. In response to a question from committee member Dr. Robert Galvin requesting more

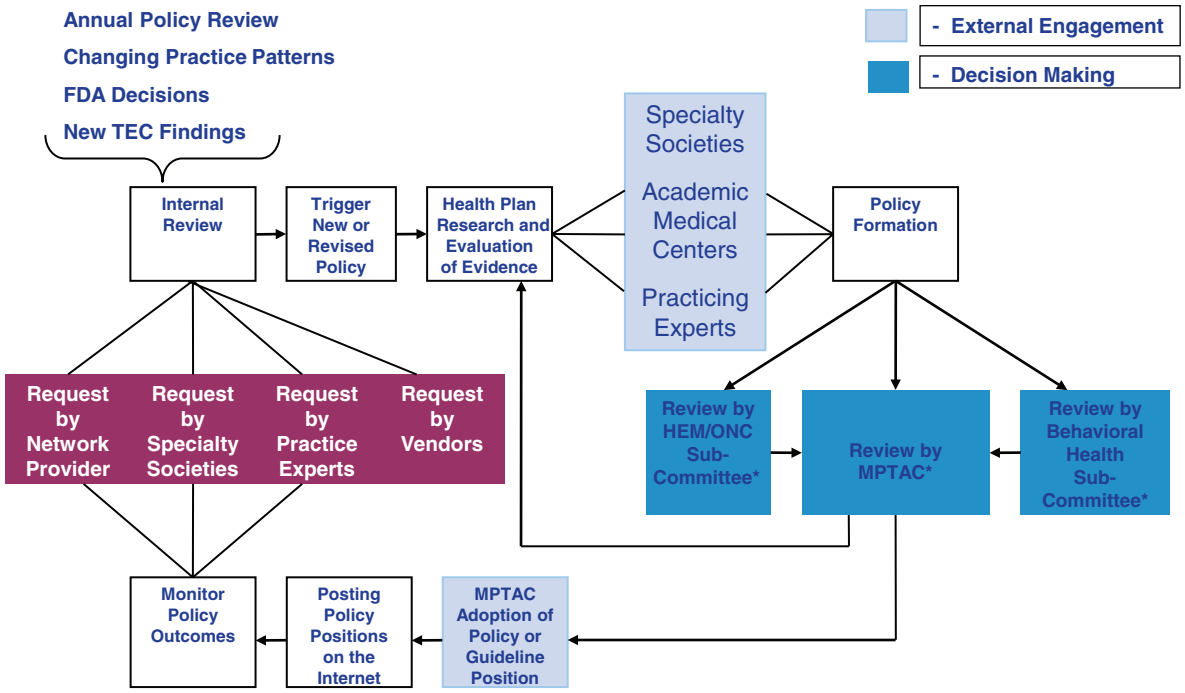

FIGURE 10-1 WellPoint, Inc. has various paths for reviewing benefit coverage to make medical policy decisions.

*Depending on the subject, different review committees will be engaged. This illustration includes the Hematology/Oncology Committee (HEM/ONC), the Medical Policy & Technology Assessment Committee (MPTAC) and the Behavioral Health subcommittee; each of these includes external physician representation.

SOURCE: Nussbaum, 2011.

specific details about who makes these evidence-based decisions, Dr. Nussbaum clarified that "for clinical decisions, we largely use external experts." For example, if a new therapy was available for cancer, WellPoint would rely on scientists and clinicians to rigorously assess the evidence for treatment.

This exchange prompted committee member Dr. Santa to explore whether the process depicted in Figure 10-1 allows providers to be "in the position of making medical necessity determinations." Dr. Nussbaum explained that WellPoint's benefit decisions and medical policies guide the medical determination. Although WellPoint has well-developed processes that allow physician-to-physician dialogue and decisions based on unique needs of the individual patient, physicians cannot make decisions irrespective of medical policy and coverage documents. Physician groups, for example, cannot independently determine that a new cancer chemotherapy is covered, but can and do contribute their viewpoints to the medical policy decision process. All evidence-based medical policies are available on the company's website.

Health Care Cost Drivers

Benefit design, Dr. Nussbaum cautioned, is not the only driver of the use of health care services. Even within the same benefits package, there is "profound variation in the use of services." This variation is not necessarily driven by what the benefit package covers. As committee member Dr. McGlynn's research has shown that patients inconsistently receive recommended care—for example, only 40.7 percent of children who saw a health care provider received recommended pediatric preventive care (Mangione-Smith et al., 2007). Dr. Nussbaum reasoned that health care utilization is also impacted by external factors such as a reimbursement system that rewards volume

over quality or outcomes, expanding capacity that triggers increased demand, patients' preferences that are not based on sufficient knowledge of the effectiveness of alternate treatments, and lack of integration and coordination among clinicians across the delivery system. Clinicians, at times, do not make decisions that are "based on the best scientific knowledge."

Complexities in Defining the EHB

Dr. Nussbaum outlined four complexities WellPoint faces in providing for the essential health benefits (EHB) defined in the Patient Protection and Affordable Care Act (ACA). First, how can WellPoint ensure that services are provided in high value centers? Second, how can WellPoint continue to focus on value-based insurance design (VBID)? Third, how can WellPoint develop benefits that meet the specific needs of diverse populations? And fourth, how can WellPoint address the variation in benefits that exists across states and employers? Dr. Nussbaum proceeded to describe how WellPoint is approaching each of these complex questions.

High Value Centers

WellPoint's network design helps to ensure the provision of high-quality care. For example, by only covering coronary artery bypass graft surgery and percutaneous cardiac interventions when performed in facilities qualified as "Blue Distinction Centers of Excellence," WellPoint's enrollees benefit from technological advances in cardiac care while WellPoint maximizes the best clinical outcomes. In addition, treatment in these Centers of Excellence costs between $4,000 and $9,000 less per event because patients have fewer complications and reduced readmissions (Nussbaum, 2011). This example shows why WellPoint has developed Centers of Excellence, particularly for transplants, cardiac and bariatric surgery, select orthopedic procedures, and rare and complex cancer treatment.

Similarly, to decrease costs and improve care, WellPoint's ambulatory services benefit design encourages cost-effective treatment by separating coverage for urgent medical needs that require emergency room (ER) services and those medical needs that do not require ER services. WellPoint spends approximately $600 every time a member visits the ER for treatment for a medical need not requiring ER services (e.g., sinusitis, pharyngitis, otitis media), whereas treatment for these common conditions in a primary care office or retail clinic costs WellPoint less than $100 (Nussbaum, 2011).

Innovation in Medical Management and Value-Based Insurance Design (VBID)

WellPoint has used innovative programs to improve health and lower long-term costs through medical management and VBID. For instance, WellPoint created a diabetes management program for a state employer in the Northeast. Among other components, the insurance product waives all co-pays for diabetes medications, steers patients to higher quality hospitals and physicians, removes deductibles for preventive care (before the ACA mandated this), and provides free telephonic diabetes education and support. While the program increased short-term costs to all parties due to increased physician visits and higher prescription drug use, Dr. Nussbaum said that his expectation is that the program is likely to demonstrate long-term savings from higher medication compliance and improved control of blood pressure and glucose, which have been shown to reduce complications of diabetes. If WellPoint had only looked at immediate affordability and prescription costs, the plan (and the employer) would have missed the opportunity to improve outcomes and reduce long-term costs.

Pharmaceutical benefit design provides another example of VBID. WellPoint's two-step design process first considers quality and outcomes and then considers cost. A clinical review committee categorizes pharmaceuticals based on research, the U.S. Food and Drug Administration (FDA) and pharmaceutical company information, and external physician input before a value assessment committee determines tier and formulary position. A WellPoint product called GenericPremium exemplifies how formulary decisions can ensure availability of all drug classes while encouraging affordability. This insurance product includes all generic drugs as well as "one or two" of the most popular branded drugs per class. Dr. Nussbaum stated that this formulary can be delivered at a 20 percent cost reduction over a more open formulary.

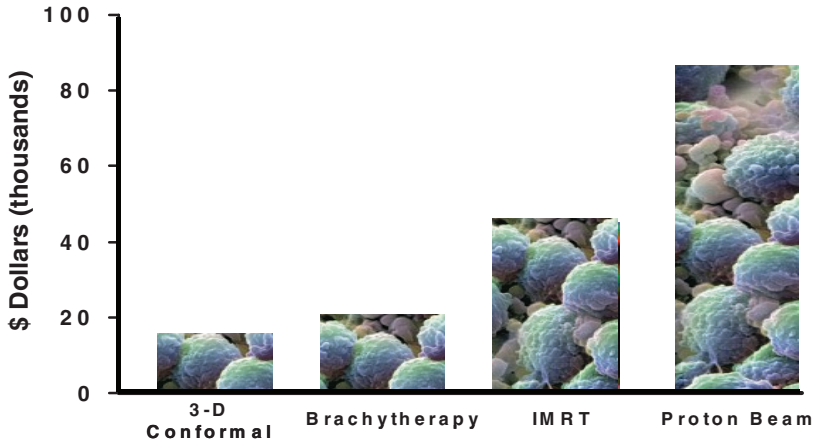

FIGURE 10-2 Prostate cancer treatments vary in cost but not necessarily in outcomes.
SOURCE: Nussbaum, 2011.

According to Dr. Nussbaum, evidence is an important component of VBID. For some indications (e.g., back pain, premature elective caesarean-section), evidence is more readily available than others. For prostate cancer, evidence does not clearly specify whether radiation therapy, medical therapy, surgery, or doing nothing is the best treatment. Furthermore, within radiation, treatments include proton beam therapy and intensity modulated radiation therapy among others. Despite the fact that proton beam therapy is nearly double the price of other therapies (see Figure 10-2), Dr. Nussbaum indicated that WellPoint would "encourage" its use if the therapy was known to be "a safer, more effective, treatment with better outcomes." In the absence of this information, however, there is little justification for the expenditure except in individualized patient circumstances.

When clinical evidence is available, as it is for the treatment and management of back pain, WellPoint uses the evidence to develop payment models that encourage evidence-based care. A study of 172,000 Anthem members revealed that care for back pain was not dependent on clinical need, but rather, on the preferences of the initial treating physician (Nussbaum, 2011). To encourage evidence-based care, WellPoint instituted bundled payments and physician education. Similarly, WellPoint's data revealed that 6 percent of neonatal intensive care unit (NICU) admissions (each of which cost over $60,000) were related to premature elective caesarean sections (Nussbaum, 2011). In an effort to prevent potentially harmful elective care, WellPoint supports patient safety initiatives that reduce premature caesarian sections. Despite American College of Obstetricians and Gynecologists (ACOG) recommendation to the contrary, approximately 36 percent of elective repeat caesarean sections are performed at less than 39 weeks of gestation (Tita et al., 2009). A future consideration for EHB could involve not covering elective caesarean sections that run counter to ACOG recommendations (ACOG, 2010).

Designing Benefits for Diverse Populations

Dr. Nussbaum explained the importance of retaining flexibility in benefits by describing the differing outcomes of African American and Caucasian women with respect to breast cancer. A study of women with breast cancer conducted by WellPoint and the American Cancer Society (ACS) revealed that insured African American women were 50 percent more likely than insured Caucasian women to have been diagnosed after Stage 2 (Short et al., 2010). These results indicate that for African American women, health insurance coverage and access were not sufficient to guarantee early diagnosis and use of specific hormonal therapies. WellPoint is deploying strategies to provide innovative education to racial and ethnic minority groups regarding the importance of breast cancer screening.

WellPoint Framework

Dr. Nussbaum concluded with WellPoint's framework for designing EHB. The pillars of this framework—delineation of health benefits, affordability, value, and flexibility for coverage of better care models as they emerge—are supported by a foundation of "proven clinical knowledge and outcomes." Flexibility, for example, allowed WellPoint to offer a product, described as "slimmed down," after the plan determined that individuals and certain employers wanted an affordable plan or they were not going to be able to afford insurance coverage. This basic plan offered only generic pharmaceuticals, preventive care, and basic hospital and physician coverage, but kept people in the insurance market.

PRESENTATION BY DR. SHARON LEVINE, THE PERMANENTE MEDICAL GROUP

Dr. Levine opened by describing some of the differences between Kaiser Permanente (KP), an integrated delivery system, and WellPoint, a health insurer: the structure of KP creates what she described as a "mutually exclusive relationship" between the delivery system—physicians, ancillary providers, and hospitals—and the health plan. She then outlined values the committee might consider in making recommendations about a process for designing benefits. First, establishing a floor for benefits across all qualifying health insurance products will promote competition based on value, quality, and cost rather than on risk selection. Second, the elimination of annual and lifetime benefit caps will protect the most vulnerable individuals. Third, the elimination of co-pays and cost sharing for preventive services will facilitate access to high-value services for prevention and early detection of diseases. And fourth, there is a need to be conscious of the "insurance effect," which has the potential to increase utilization and costs.

Mandates to provide first-dollar coverage for goods or services previously paid for by consumers or available over-the-counter (and thus not covered by an insurance benefit) eliminate any economic barrier to accessing the service or acquiring the products; therefore, first-dollar coverage is beneficial in terms of facilitating access (e.g., to desirable preventive services), but can induce price-insensitive demand. Mandates to cover, for example, "all drugs in a class," eliminate the need for manufacturers to compete for inclusion in a formulary or preferred drug list based on price, and provide the manufacturer significant and relatively unrestrained pricing power because patients, physicians, and hospitals do not feel the cost impact directly.

Dr. Levine elaborated on challenges KP faces with regards to the third issue: co-pays for preventive services. The ACA does not specify whether surveillance is a diagnostic benefit or a preventive benefit. Surveillance occurs once risk factors are associated with a patient (as a result of a procedure or a family history). The frequency of surveillance and the technologies chosen for screening vary and have cost implications if co-pays and co-insurance are waived, and have utilization impacts if they are not waived and not treated as preventive services. Dr. Levine suggested that the U.S. Department of Health and Human Services (HHS) consider whether and under what circumstances surveillance should be treated as a diagnostic benefit or a preventive benefit so that all carriers and health insurance products adopt the same approach. For example, fecal occult blood testing for colorectal cancer screening is covered as a preventive service. A positive test requires a follow-up colonoscopy, which could be treated as an extension of the preventive screening, with no cost sharing, or as a diagnostic service in follow up to a positive preventive screening. The former approach will eliminate economic barriers to completing the investigation, and also eliminate any incentive to replace fecal occult blood testing for preventive screening with colonoscopies in all cases. The latter approach could eliminate interest among physicians and patients to continue to use fecal occult blood testing, but proceed directly to colonoscopy to avoid the potential for patient exposure to cost sharing in the face of a clinical finding. Similarly, a benign polyp found and removed on routine colonoscopy dictates a different interval for repeat testing—a risk factor for colorectal cancer is identified, but no disease is found. Is the repeat colonoscopy at an earlier interval still a screening procedure or, as enhanced surveillance, is it now a diagnostic procedure? A standardized approach across carriers and products will be important for consumers.

Decision Framework for Covered Benefits

Dr. Levine proceeded to describe the decision framework KP uses to determine its covered benefits, update benefits, and change cost sharing. The framework is principally used when adding benefits; benefits are rarely removed though services may no longer be provided or prescribed because of changes in science and evidence. KP considers:

- Whether the benefit is a health care service. If so, would it improve or maintain health or prevent disease or deterioration and would it be provided by a licensed health care provider.
- The strength of the evidence for a health benefit.
- The impact on cost of the benefit package. Dr. Levine stated, however, that KP does not make coverage decisions based on cost.
- The social insurance question: is it is reasonable to ask others in the risk pool to subsidize the cost of providing the benefit?

Committee member Dr. Galvin asked for additional details about who makes these coverage decisions. Dr. Levine responded that "the decision makers in KP are both clinicians and folks from the health plan insurance business side." For example, when clinicians, dermatologists, and rheumatologists wanted to increase access to UV therapy for psoriasis, they met with the health plan's contracts and benefits committee and the decision was jointly made to increase access by eliminating co-pays for this therapy. These decisions are internal to the organization, balancing what the providers recommend with what patients desire and what the plan determines is beneficial.

Given the potential risk of adverse selection, KP also considers what else is available in the market when making benefit decisions. For example, she said that KP "fought long and hard to eliminate the option of insurers selling products in the individual market in California that did not have maternity coverage." But if competitors offer products without maternity coverage (a less expensive product), KP loses the ability to enroll those individuals looking for the less expensive health insurance product and disproportionately enrolls those intending to, or more likely to use the maternity coverage. Dr. Nussbaum supported Dr. Levine's position, describing a situation in which WellPoint was the only plan offering bariatric surgery in several markets. Due to adverse selection, offering this benefit was "not sustainable."

Medical Necessity Decisions

KP uses what Dr. Levine described as "a common definition" of medical necessity (for further discussion of medical necessity, see Chapter 5):

> medically appropriate and indicated and required to prevent, diagnose a condition or clinical symptom in accord with generally accepted professional standards of practice and consistent with standards of care in the community.

KP's physicians are "involved on a daily basis in determinations of medical necessity" for otherwise contractually covered benefits and in their practice. In response to a question from committee member Dr. Santa, she clarified the intersection of coverage and medical necessity: "medical necessity determination is only for otherwise covered services," and physicians do not "make, prescribe, perform, or offer services not covered" under the benefits package. Her response prompted Dr. Santa to ask about the impact of physicians making these medical necessity decisions. The KP system, Dr. Levine said, creates "an environment of examined practice and constant peer interaction. So it is not individual physicians somewhere just determining that this is right or wrong. There is a fair amount of collective engagement in that process."

That said, if a physician determines that a treatment is not medically necessary and the patient disagrees, an appeals process is in place. Dr. Levine described this process as follows: the patient can appeal, and if the plan upholds the physician's determination at the medical center level and regional level, then the member's appeal goes to the regulator (in California, the regulator is the Department of Managed Health Care). If the regulator determines the appeal is related to a coverage issue, the regulator makes the decision. If the regulator determines the appeal is a medical necessity issue, the determination goes to independent external medical review (Chapter 12 further describes California's review processes for managed care).

Variation in Benefits and Benefit Design

Dr. Levine then described the degree of variation in benefits among KP plans and the reasons for this variation. She stated that plans vary in cost sharing, deductibles, co-insurance, and out-of-pocket maximums, with deductibles ranging from $250 to $5,000 for individuals and from $500 to $10,000 for a family insurance product (Levine, 2011). Beyond these benefit design elements, some variation results from contractual exclusions and different state mandates in the actual benefits covered.

Contractual Exclusions

Dr. Levine said that unlike the self-insured market, KP's fully insured model provides limited ability to use criteria-based coverage (e.g., when a plan only covers spine surgery after meeting certain criteria) and "limited ability to customize exclusions." Services are either covered under the contract or excluded. Approximately 25 percent of KP's purchasers accept KP's exclusions "as-is," while 50 percent expand the list of exclusions, and 25 percent opt to either "buy up or limit the number of exclusions." Exclusions tend to fall into one of three categories: they are not a health care service, they do not pass the "social insurance test," or they are excluded based on the site of care.

Non-health care services, for KP, include teaching Braille or American Sign Language, exercycles, gym memberships, and personal trainers, among others. While exercise options could be beneficial to health, Dr. Levine said KP does not view them as a part of health care delivery nor does it consider certain types of educational interventions—for example, interventions that improve functioning and productivity in persons who are blind or hearing impaired—part of health care delivery. Some educational services such as diabetes or asthma self-management training are covered services, as they are directly related to medical care and clinical outcomes.

Social insurance test exclusions are more subjective. This test asks whether "it is fair to ask others in the risk pool to subsidize or provide coverage for something" even if this service must be provided by a physician. Cosmetic services, reversal of voluntary sterilization, growth hormone as a performance enhancer in adults, and assisted reproductive technologies often fail the "social insurance test" as they are not "generally accepted" for coverage given "today's societal norms." In general, these are considered life-enhancing rather than medically required to maintain or improve patient health. Some of these procedures, though, must be covered in particular states because of state mandate requirements. Massachusetts, for example, requires coverage of unlimited cycles of assisted reproductive technology.

When committee member Ms. Ginsburg later asked for additional details on the "social insurance test," Dr. Levine cited KP's approved exclusion of the drug Pleconaril for treatment of common cold symptoms as an example of a social insurance test exclusion. Pleconaril, an antiviral agent effective against picornaviruses, was expected to cost $75 for approximately 48 hours of symptom mitigation for viral upper respiratory illness. KP feared the "insurance effect" would raise costs and induce utilization disproportionate to the clinical benefit derived, given that most colds resolve within the 48-hour timeframe without such intervention. Ultimately, the regulator approved exclusion of the drug from coverage based on the social insurance argument.[1]

Site of care exclusions usually relate to coverage by a non-plan provider that was not authorized as a referral, an emergency, or an out-of-area urgent need.

State Mandates

Dr. Levine concluded her presentation by pointing out that there is wide variation in state mandates; she characterized these as mandates "to cover," mandates "to offer," and mandates "to provide." Mandates to cover as part of the benefit package relate to the service itself, the frequency, or the site of service. Many states, for example, mandate coverage of annual PSA (prostate-specific antigen) testing, and California mandates coverage of diabetes equipment and supplies, reconstructive surgery, and cancer clinical trials, among others. Maryland, in what Dr. Levine called a "singular" requirement, mandates coverage of a wig for patients who have lost hair as a

[1] At the time of this presentation, the drug had not received FDA approval for the treatment of upper respiratory infections, and the exclusion for drugs intended to lessen the symptoms of viral upper respiratory infections remains.

result of cancer chemotherapy. Many states have mandates "to offer" services such as orthotics and prosthetics. A mandate to offer requires the carrier to offer to sell, outside the basic benefit package, a supplemental benefit at an actuarially sound price. Mandates to provide are rarer and often occur within the context of care delivery. An example would be a mandate to provide a specific service (e.g., interpreter services) or a product when a diagnosis is made (e.g., a specific set of information produced by a federal or state agency relating to the condition).

For a closed network, integrated delivery system like KP, any willing provider and any willing pharmacy mandates are particularly problematic. KP's ability to deliver coordinated care across the continuum, with close linkages among primary care, specialty care, ambulatory, and inpatient settings depends on having a dedicated delivery system in which all parties have the same incentives, access to the same information and the same information platforms, and operate in a linked and coordinated fashion based upon a consistent set of values relating to quality, safety, evidence, and resource stewardship. Dr. Levine said that this becomes very difficult to sustain in an "any willing provider" environment.

State mandates are a concern for plans, Dr. Levine said, not only because of state-by-state variation, but also because they tend to be static. The dynamic nature of science and technology means that guidelines evolve and practices change; once state mandates appear, however, they are rarely repealed. Georgia, for example, still mandates that plans offer coverage for autologous bone marrow transplant (ABMT) for breast cancer (NAIC, 2009), despite the fact that this treatment was found to be less effective than conventional therapies and harmful to patients (Stadtmauer et al., 2000). Given the evolving nature of science and technology, Dr. Levine suggested that the committee consider "how granular to get" in mandating specific EHB benefits: "the more granular, the more often they'll need to be revisited." She suggested, for example, that cancer screening mandates be broad because if specific technologies for cancer screening are mandated, many of these will be "obsolete long before anyone thinks to look at the regulation."

Committee member Mr. Koller asked both Drs. Levine and Nussbaum how they would propose addressing this state-by-state variation in mandates if they were developing the EHB design. For mandates in which there is "absolute proof that something is beneficial," Dr. Nussbaum recommends a "national coverage model." Conversely, he said, for areas in which benefits are unproven or rapidly evolving, flexibility at the state and federal coverage levels may be necessary. Dr. Levine suggested that criteria regarding the level of evidence needed to mandate a benefit would be beneficial, as would "resistance to granularity." Broader mandates, such as mandated coverage for cancer screening, would be more beneficial than mandated coverage for PSA testing for prostate cancer.

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11

Deciding What Is Essential and Evidence-Based in Two States for Public Insurance Programs

The determination of essential health benefits (EHB) will have an impact, directly or indirectly, on state-sponsored insurance programs of all sorts. Carolyn Ingram, the senior vice president of the Center for Health Care Strategies (CHCS) and formerly the director of New Mexico Medicaid and the State Children's Health Insurance Program (SCHIP) first focused on the implications of EHB for Medicaid, Medicaid expansion programs, and offerings through the upcoming health insurance exchanges. She also drew on knowledge of transitions of low-income people migrating from a New Mexico Medicaid expansion program, called State Coverage Insurance, to employer-sponsored insurance and vice versa. Jeffery Thompson is the Chief Medical Officer of Washington State's Department of Social and Health Services and the Health Care Authority, which operates the state's Medicaid program, an expansion program for low income individuals not eligible for Medicaid called Basic Health Plan, and the state employee benefits program. He discussed how state-covered plans employ evidence to make coverage decisions. Leah Hole-Curry, program director of the Washington State Health Technology Assessment (HTA) Program provided further guidance on the independent review process and criteria used to evaluate new technologies for coverage in that state. This program operates within the Health Care Authority and impacts coverage for Medicaid and other state purchased health care (e.g., state employees', retirees', correctional inmates', and worker's compensation benefits).

PRESENTATION BY MS. CAROLYN INGRAM, CHCS

Ms. Ingram began by describing the differences between traditional Medicaid, the Medicaid expansion under the Patient Protection and Affordable Care Act (ACA), and the private health insurance offered in the state exchanges created by the ACA. She described the three programs depicted in Table 11-1 as "zones" through which individuals will move. A person might begin in traditional Medicaid, move into the Medicaid expansion group, and then be eligible for coverage in an exchange as their economic situation changes. This "churn" or "migration" between the different programs presents both challenges and opportunities as each program has slightly different requirements and will be impacted differently by the introduction of the EHB. Ms. Ingram expressed concern that if the packages differ in benefits, people might not "want to migrate out of the Medicaid program and into the exchange or vice versa." As different benefits might be more of an attraction to different customers, she suggested that the committee consider the comprehensiveness of EHB compared not only to a typical employer plan but also to traditional Medicaid and existing Medicaid expansions. Based on current Medicaid experiences, as many as 50 percent of enrollees will annually move in or out of the program (Sommers and Rosenbaum, 2011).

TABLE 11-1 Traditional Medicaid, Medicaid Expansion, and Exchange Plans Vary in Population Served and Benefits Offered

	Traditional Medicaid	Medicaid Expansion	Exchanges
Population	Varies (mandatory and optional)	Uninsured up to 133% FPL	Individuals above 133% FPL
Benefits	Mandatory and optional benefits with EPSDT requirements for children	Benchmark or equivalent that must include EHB and some traditional Medicaid services	Essential health benefits as a floor for qualified health plans
Delivery System	Mix of fee-for-service and managed care	Same as traditional Medicaid	Qualified health plans
EHB Issues	Comprehensive EHB could be more or less generous than traditional Medicaid	EHB promotes coordination with exchanges, but may be different from "benchmarks"	Fine line between comprehensiveness and affordability

SOURCE: Ingram, 2011.

Understanding the Medicaid Landscape

Ms. Ingram first clarified the difference between three state programs for lower-income individuals. Traditional Medicaid has defined mandatory[1] and optional[2] benefits, including EPSDT (early periodic screening, diagnosis, and treatment) requirements for children. The Medicaid expansion mandated by the ACA will be layered on top of traditional Medicaid to provide coverage for individuals up to 133 percent of the federal poverty level (FPL),[3] while the exchanges will provide subsidies for individuals between 133 and 400 percent of the FPL.[4] These expansions might take the form of Medicaid benchmark,[5] benchmark-equivalent,[5] or state basic health insurance designs;[6] these expansions, plus the plans offered in the exchanges, must all include the EHB.

Under the Deficit Reduction Act of 2005,[7] benchmark plans were first authorized for state Medicaid programs as a method of cost containment by allowing slimmer benefits than traditional Medicaid. These plans could offer benefits benchmarked to the benefits offered to: (1) federal employees though the federal program's standard Blue Cross Blue Shield plan, (2) state employees in the state, or (3) enrollees in the largest commercial health maintenance organization (HMO) in the state. Additionally, other plans could be used as a benchmark provided the plan is certified "actuarially equivalent" to one of the benchmark plans (these actuarial equivalence plans require a waiver from the Secretary of the U.S. Department of Health and Human Services [HHS]). Eleven states use a benchmark plan, and several others have actuarially equivalent plans (i.e., benchmark-equivalent plans) (CMS, 2009).

Ms. Ingram stated that benchmark plans are generally less comprehensive than traditional Medicaid plans as they "tend to be more commercial in their coverage." Benchmark plans have historically included: inpatient and outpatient hospital services; surgical and medical services; laboratory and x-ray services; well-baby and well-child care, including age appropriate immunizations; other preventive services, as designated by the Secretary; and rural health clinic and FQHC (federally qualified health center) services. But when the ACA provisions go into effect in 2014, these benchmark plans will also have to include categories of care not in typical commercial employer plans, just as the exchange plans will have to do.

Ms. Ingram noted that most states have used benchmark plans not as an overall cost containment strategy, but rather, to expand coverage to previously uncovered populations (e.g., to childless adults, parents, or expanded

[1] Mandatory benefits under Medicaid include physicians' services, laboratory and x-ray services, inpatient and outpatient hospital services, family planning services and supplies, rural health clinic services, nurse midwife services, and long-term care services (nursing facility services and home health services) (KFF, 2001).

[2] Optional benefits may include prescription drugs, dental services, prosthetic devices, eyeglasses, diagnostic, screening, preventive, and rehabilitative services, personal care services, hospice care (KFF, 2001).

[3] Patient Protection and Affordable Care Act of 2010 as amended. Public Law 111-148 § 2001 (a)(1)(C), 111th Cong., 2d sess.

[4] § 1401(a) amending Internal Revenue Code by inserting § 36B.

[5] § 2001.

[6] § 1331.

[7] Deficit Reduction Act of 2005. Public Law 109-171 § 6044, 109th Cong., 2d sess. (February 8, 2006).

child populations). But as states have faced budget constraints, they have reduced basic Medicaid programs and adopted benefit packages that look more like benchmark plans.

State Basic Health Plans

State basic health plans are an option for individuals between 133 and 200 percent of the federal poverty level (FPL)[8] (replacing the exchange subsidy for that population[9]). These must be delivered through contracts with private health plans (with at least an 85 percent medical loss ratio). They must include the EHB and are subject to the premium and cost-sharing limits in the ACA. The state receives 95 percent of the subsidy that consumers otherwise would have received through the exchange.

Designing a New Mexico Medicaid Expansion Plan

New Mexico's State Coverage Insurance (SCI), initiated in 2005, is an expansion program on top of the base Medicaid program developed to address New Mexico's high rate of uninsured individuals and low rate of employer-sponsored coverage. The program has no pre-existing condition limitations and covers childless adults and parents up to 200 percent of the FPL, with what Ms. Ingram called "generous income disregards" that allow coverage for individuals above 200 percent of the FPL. The vision was that an individual not covered by his employer could enroll in the SCI, and then, as he received promotions and had higher earnings, he could seamlessly move onto his employer's plan. To coordinate the SCI program with employer-sponsored care, the state Medicaid office contracted with major managed care companies in the state. Committee member Dr. Chernew later requested information about how New Mexico managed its relationships with these companies to ensure the companies were as dedicated to evidence-based care as the state agency. In response, Ms. Ingram said, "it really gets down to the contract management . . . you cannot design it all in the benefit package."

To make the SCI program affordable, the state instituted a $100,000 annual cap on coverage (New Mexico Human Services Department, 2011), but few enrollees have reached that limit. If the enrollee loses his job or gets sick, he can transition, Ms. Ingram said, to traditional Medicaid or to the New Mexico High Risk Pool, both of which have more comprehensive benefits. Figure 11-1 compares the SCI benefits with those of traditional Medicaid and indicates that SCI benefits are less comprehensive. In response to a question from committee member Dr. Sandeep Wadhwa, Ms. Ingram provided some examples of SCI benefit limits, including a 25-day inpatient limit and limits on durable medical equipment. In these instances, the state relies on the managed care companies for utilization review.

Ms. Ingram stated that under the SCI program, individuals with low incomes and disabilities get more comprehensive benefits than individuals at higher incomes. This notion is contrary to typical employer plans, where people at higher incomes are able to purchase more coverage. But for Medicaid, "when dealing with populations with disabilities at lower income levels, it makes sense to have insurance packages that are richer," said Ms. Ingram.

When the SCI was initially unveiled, people with complex needs enrolled first. After five years, though, Ms. Ingram noted that demand and costs have leveled, though not surprisingly, pharmaceuticals and hospital care "are the biggest cost drivers." As Ms. Ingram was redesigning the program, she conducted focus groups around the state to gain a sense of what people liked and disliked about the benefit package. Her principal finding was that SCI enrollees were "thrilled to have the coverage and did not want it to ever go away." She also found that enrollees wanted vision and dental benefits and expressed willingness to pay higher premiums for these supplemental services.

Considerations for the Committee

In Ms. Ingram's current role at the CHCS, she works with states to address their concerns related to the Medicaid expansion under the ACA. States have expressed to her that if the EHB include benefits not currently covered by

[8] Patient Protection and Affordable Care Act of 2010 as amended. Public Law 111-148 § 1331, 111th Cong., 2d sess.
[9] § 1331 (d)(3)(A).

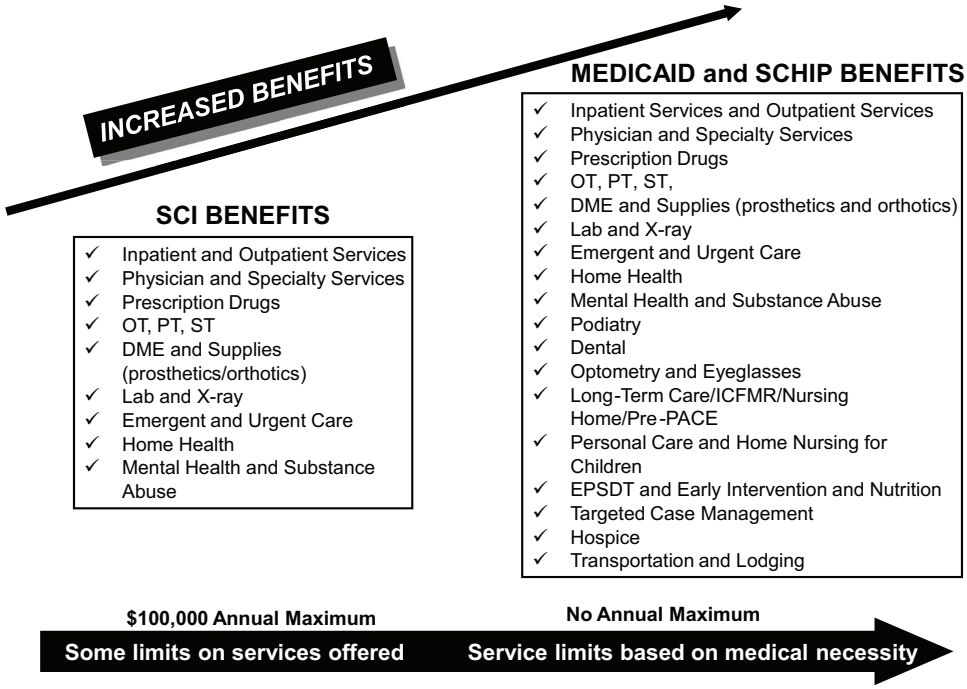

FIGURE 11-1 New Mexico's traditional Medicaid has a broader array of benefits than the State Covered Insurance (SCI) Program.
SOURCE: Ingram, 2011.

traditional Medicaid, then states are unclear if they will have to add these additional benefits. In response to an inquiry from committee member Mr. Schaeffer, Ms. Ingram indicated that while nothing in the ACA addresses this uncertainty, she believes states would probably have to add the EHB to ensure equity: "how could you have somebody at a higher income level getting essential benefits that are not offered in the traditional Medicaid program?" States are attempting to contain costs and continued expansion of benefits raises concerns. Ms. Ingram said, for example, that most states do not currently offer habilitation services to their traditional adult Medicaid population; if these services are mandated as an essential benefit for Medicaid programs, states will have higher Medicaid costs.

Ms. Ingram said another area of state concern is what happens when the 100 percent federal matching rate for new enrollees in the ACA-mandated Medicaid expansion ends.[10] States already covering some or all of the population up to 133 percent of the FPL (e.g., New Mexico, which provides coverage under SCI) are unsure if they will get the increased (i.e., 100 percent) match for the people already enrolled or only for new enrollees. States are also concerned that this 100 percent match for Medicaid expansion programs is not sustainable.[11] Thus, Ms. Ingram said, benefit decisions must consider the long-term costs for states in the absence of the federal match.

Ms. Ingram said the benefit programs described in Table 11-1 have to be designed to meet the needs of a wide variety of individuals who move through and across these programs. The definitions of EHB are going to have a long-term impact on Medicaid costs for not only the expansion population, but also for the traditional Medicaid program. A number of coordination options can minimize the impact of program churn on recipients and program

[10] § 2001(y)(1)(A).

[11] The 100 percent match for the Medicaid expansion will last from 2014-2016, decreasing to 95 percent in 2017, to 94 percent in 2018, to 93 percent in 2019, decreasing to 90 percent in 2020 and each year thereafter (§ 2001(y)(1)(A)-(E)).

administrators: aligning benefits and provider networks, requiring plans to offer products for Medicaid and the exchange, and offering continuous eligibility to reduce migration frequency from program to program.

PRESENTATION BY DR. JEFFERY THOMPSON, WASHINGTON STATE DEPARTMENT OF SOCIAL AND HEALTH SERVICES

The Washington State Department of Social and Health Services operates the state's Medicaid program, state employee benefits program, and basic health plan. Dr. Thompson principally focused on how his office uses evidence to define benefits for these state-covered programs and plans and to establish the basis for medical necessity decisions.

Six years ago, Dr. Thompson and his colleagues began developing an evidence-based benefits system by meeting with interested stakeholders, including legislators, providers, and beneficiaries, to develop a definition of evidence-based benefits and a transparent hierarchy of evidence used to make benefit decisions. They defined benefits that offer access to affordable quality health care for the population served. These benefits, he said, use "the best evidence of proven value to the population," and are codified in administrative code.[12] These evidence-based medicine (EBM) rules are the result of 18 months of work with community and state legislative and gubernatorial staff, medical and hospital associations, and patient advocates. The key principles for the design process were: consistency of decisions, transparency of decisions, evidence-based, and focus on patient safety.

Hierarchy of Evidence in Benefit Decisions

Figure 11-2 describes the hierarchy of evidence. For example, if a service is supported by "A-level evidence based on randomized trials," the service is likely to be added to the benefit package because, as stated by Dr. Thompson, the evidence supports that the plan "should pay for it." Before the introduction of the evidence-based benefit design, cardiac rehabilitation was not a covered benefit. Once reviewed, however, A-level evidence showed cardiac rehabilitation helped avoid further surgery, hospitalization, and subsequent heart attacks; the benefit is now covered. Similarly, before evidence-based decisions were instituted, bariatric surgery was covered for numerous indications despite a 40 percent mortality rate at some hospitals. A review of the evidence revealed that bariatric surgery is indicated for some conditions (e.g., BMI > 35 with diabetes, and/or joint replacement), but not all patients. By limiting coverage to specific indications, the department reduced case costs by half (from $36,000 to $17,000) and improved outcomes; he reported that the state-covered plans have not had any bariatric surgery-related deaths in seven years. Dr. Thompson provided this example as a way to caution the committee: some benefits that do not have limits may have unintended consequences. However, use of evidence can balance access, quality, and costs.

The department generally approves benefits supported by A- and B-level evidence, but does not necessarily reject benefits with only C- and D-level evidence. For example, if a provider can prove that a service supported by inconsistent, C-level evidence is "less costly, less risky, and is the next step in reasonable care," then coverage may be considered. For example, a PET scan for a cancer diagnosis may have limited or no outcome studies, but in special cases can reduce the costs and risks of a surgical procedure or is the second exam when conventional exams are inconclusive.

Additionally, the state-covered plans may be willing to cover some experimental, D-level treatments provided the treatment is approved by an internal review board, the treating physician is in the study, and the patient has provided informed consent. Certain rare conditions may never have A-level studies, Dr. Thompson said. He cited the coverage of experimental treatments for a young adult patient with generalized dystonia to highlight the upside of covering experimental therapies: while the patient's treatment has been "quite costly," Dr. Thompson said, "that is fine because he has been enrolled in studies where we are trying to figure out what is the appropriate therapy."

[12] Washington Administrative Code, 388-501-0165 (1994).

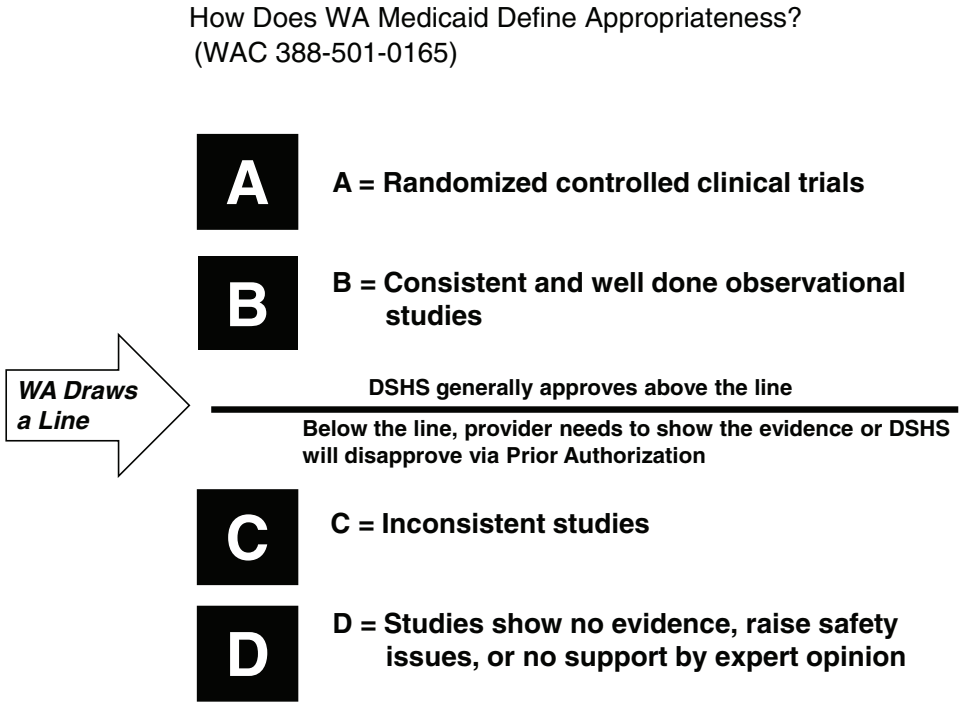

FIGURE 11-2 The Washington Department of Social and Health Services uses levels of evidence to choose covered benefits. SOURCE: Thompson, 2011; *Washington Administrative Code,* 388-501-0165 (1994).

Evidence-Based Pharmaceutical Benefit Decisions

The idea of "above the line" (i.e., supported by A- and B-level evidence) and "below the line" (i.e., supported by C- and D-level evidence) benefits has also been adapted for application in pharmaceutical benefit design. Cost is an additional criterion that the department uses to weigh generics against brand name drugs. For the proton pump inhibitor (PPI) class of drugs, for instance, where there are several branded drugs available, the state-covered plans have based coverage on the least costly yet equally effective treatment. Figure 11-3 shows the drugs within this class and their comparative cost. Dr. Thompson asserted that while there is no evidence of increased effectiveness across these drugs, there is a nine-fold difference in prices. Some state employers have chosen not to cover PPIs, instead forcing beneficiaries to pay for Prilosec over-the-counter. Washington's traditional Medicaid plan covers both generics and branded drugs in a tiered formulary and the state's basic health plan has a $10 co-pay for drugs "above the line" (e.g., omeprazole) and a 50 percent co-pay for drugs "below the line" (e.g., Prevacid). Dr. Thompson suggested that the nation can save a great deal in health care expenditures without reducing quality by requiring that newer drugs have head-to-head comparisons rather than simply being tested against a placebo. The use of cost comparisons and evidence can also be applied to other benefits and services.

Medical Necessity Appeals

When committee member Dr. Selby asked Dr. Thompson to gauge the success of this evidence-based benefits program in making medical necessity determinations, Dr. Thompson described the state's appeals process

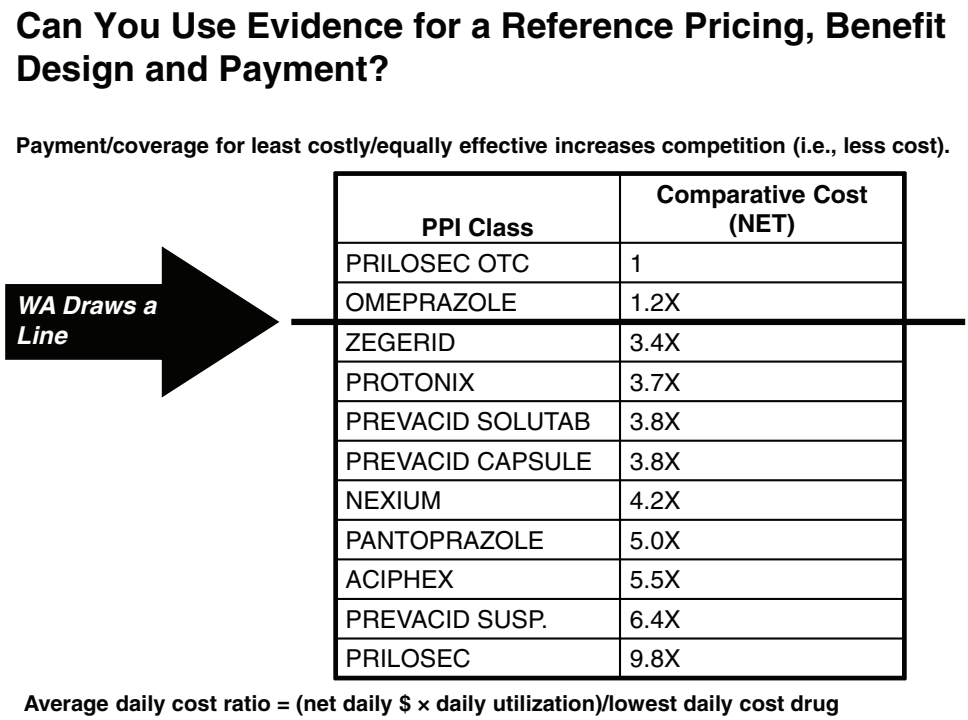

FIGURE 11-3 The Washington Department of Social and Health Services considers comparative costs to a reference price when designing pharmaceutical benefits and payment.
SOURCE: Thompson, 2011.

and vouched that appeals have decreased under the evidence-based model. In Washington, enrollees in the state's entitlement programs can appeal to administrative law judges. According to Dr. Thompson, the state prevails 98 to 99 percent of the time for cases that are unrelated to durable medical equipment, principally because administrative law judges understand the evidence-based benefit system.

Challenges of an Evidence-Based Benefits System

Committee member Dr. McGlynn commented that Washington's evidence-based benefit system is "elegantly designed" but questioned Dr. Thompson about on-the-ground challenges. In response, he stated that as a steward of the public's money, he must control access, quality, and cost, all of which are "moving targets." He principally does so by aiming to control pharmaceutical, hospital, and outpatient expenses because if he does not control these three domains, the system will not be "affordable to anybody." The state communicates these opportunities and comparisons to providers via newsletters and feedback reports with great success. Furthermore, Dr. Thompson described instances in which the evidence hierarchy does not provide all of the information needed for benefit design. For example, when one randomized controlled trial (RCT) supports one treatment and another RCT supports a different treatment, the department has to compare the two, often by looking at which one is "more expensive than the other one" provided "they have equal outcomes." Comparative effectiveness research (CER) could provide important insights into these determinations, but despite a "push toward" CER, implementing in practice "is very difficult to do," without good systems that are transparent and non-biased. Back surgery evidence, for example,

is one instance with conflicting evidence: half the patients get better after surgery and half get worse. Weighing such conflicting evidence when designing benefits is inherently challenging.

Additionally, regardless of the level of evidence, the state-covered plans have had to "draw some lines." Dr. Thompson stated that as technologies continually advance, the plans have had to consider "function and cost." For example, once a patient has had bariatric surgery, he may also need a panniculectomy to remove excess skin. The coverage for this additional procedure may be weighed against whether any functional, not just cosmetic, benefit ensues.

Furthermore, he said, some plans have imposed limits on services such as occupational and physical therapy. State Basic Health beneficiaries under the Medicaid expansion, for instance, are covered for 12 visits (i.e., up to a combined maximum of 12 therapy visits per year with no more than six being for chiropractic care; visits qualify only when used as post-operative treatment following reconstructive joint surgery and must be within one year of surgery).

Additional challenges relate to the kind and quality of available evidence. For example, Dr. Thompson does not believe "placebo studies should be good enough anymore." Additionally, even among evidence-based practice centers, there is no consensus on how to define biased research; however, he understands that the Institute of Medicine (IOM) is making recommendations to guard against biased guidelines that will better inform providers and patients (IOM, 2011). Dr. Thompson noted that making transparent decisions about the evidence is one way to account for these challenges.

PRESENTATION BY MS. LEAH HOLE-CURRY, WASHINGTON STATE HEALTH TECHNOLOGY ASSESSMENT (HTA) PROGRAM

Leah Hole-Curry began by describing the role of health care spending in Washington State's current fiscal crisis. The state has a projected budget shortfall of $3 billion for 2011-2013. Thirty-three percent of the state's 2010 budget was spent providing medical care to 1.5 million Washington residents compared with 20 percent of the budget in 2000 (Hole-Curry, 2011). The emergence, adoption, and widespread diffusion of new technologies, she said, contribute to excess cost growth; while these technologies are "important to celebrate," they are also a "cause for deep concern for our nation." Thus, HTA, which is statutorily mandated to make transparent, independent assessments related to coverage decisions, must consider cost and value in its benefit decisions.

HTA's Review Process

Ms. Hole-Curry proceeded to describe the HTA and explain its process and criteria for reviewing technology coverage. This independent office resides within the state's Health Care Authority. The HTA administrator selects technologies to review based on nominations from plan medical directors and members of the public. The technology assessment process takes two to eight months, including 100 days for public comment, which, while slowing the process, improves its transparency. Since 2007, $27 million in savings is attributed to HTA's work.

Because HTA's mission to determine if health services paid for by state government are safe and effective may be mistakenly construed as "imposing limits," committee member Dr. Sabin asked Ms. Hole-Curry how she gains public acceptance of HTA's work. In response, Ms. Hole-Curry described the evolution of the program: when it first began in 2006, provider groups, in particular, "fundamentally resisted" the concept by speaking out against policy decisions that would impact patient care. Since then, resistance has diminished, and provider groups more often question HTA's specific research methods and suggest "more appropriate studies" that HTA should consider. Complaints about HTA's role and processes do, though, continue to come from industry, manufacturer associations, and some subspecialty provider organizations.

HTA's Review Committee

During HTA's review process, an 11-member clinical committee holds a public hearing to review the evidence about a particular technology. The clinicians on the committee must be from the state of Washington, cannot be

associated either with a state agency or with the manufacturer of the product, and have to be actively practicing. These requirements make the clinical committee "different than other programs" because the committee is comprised of practicing providers and because its decisions are made in an open, public meeting. When committee member Mr. Schaeffer probed for details about the role of politics in shaping the decisions of this committee, Ms. Hole-Curry noted that while committee members are appointed by the head of the Washington Health Care Authority, the committee is shielded from legislative and political influence. If a legislator wishes to provide comments to the committee, for example, the legislator speaks to a member of the HTA program staff who then provides these comments to the committee during the public comment period.

The decisions rendered by the clinical committee are binding on all three of HTA's governed programs (i.e., Medicaid, worker's compensation, and the public employees' program). In some unique instances, Ms. Hole-Curry said, decisions irrelevant to the program need not be implemented (e.g., the worker's compensation program did not need to implement pediatric bariatric surgery coverage).

Evidence for Use in Policy Decisions

HTA's clinical committee, Ms. Hole-Curry said, relies on multiple sources of data (including an evidence report provided by the vendor and public testimony) and a "very basic hierarchy of evidence" to make its coverage decisions (Box 11-1). The committee uses specified criteria to translate this data into useable findings. First, the committee considers efficacy and safety to determine the degree of variation between how the technology functions in the "best environments" and the "real world." Only after a technology has "passed" the tests of effi-

BOX 11-1
Criteria Used by the Washington State Health Technology Assessment Program to Make Coverage Decisions

- **Efficacy**
  - How technology functions in "best environments"
    - Randomized trials distinguish technology from other variables
    - Meta-analysis
- **Effectiveness**
  - How technology functions in "real world"
    - Population level analyses
    - Large, multicenter, rigorous observational cohorts (consecutive patients/objective observers)
- **Safety**
  - Variant of effectiveness
    - Population level analyses
    - Case reports/series, FDA reports
- **Cost**
  - Direct and modeled analysis
    - Administrative/billing data (charge vs. cost)
- **Context**
  - Mix of historic trend, utilization data, beneficiary status, expert opinion

SOURCE: Hole-Curry, 2011.

cacy and safety does the committee consider "the cost question." Of the 20 evaluations HTA has undertaken, the committee has considered cost for only "a few," either because the technology has not gotten through the "first two hoops," or because the "first two hoops answer the question and cost becomes immaterial because there is value that's uniquely provided by the technology." When Ms. Ginsburg asked for clarification whether the HTA has ever used cost-effectiveness in determining whether to accept or deny a new treatment, Ms. Hole-Curry cited a decision in which the clinical committee "shelved" virtual colonoscopy until evidence could demonstrate it was less expensive than equally effective alternatives. In this case, the committee found that the safety and efficacy of virtual colonoscopy was equivalent to existing covered tests, and that patient preference was approximately the same for all test options. The virtual colonoscopy, however, was more expensive and recommended every five years compared to every 10 years for existing covered tests, so the committee ruled that it would not be covered until it was deemed less expensive than equally effective alternatives.

Key Learnings

In advising the committee to avoid "hardening in our system a benefit that we know is ineffective," Ms. Hole-Curry emphasized "our current system has both very great things and a lot of things that are not working." She proposed four principles that the committee could consider in developing evaluation criteria: (1) aim to develop a learning system, (2) be transparent, (3) develop an evidence base but keep in mind that evidence is "not sufficient," and (4) have demonstrable evidence of equivalence. She noted that multiple entities reach different decisions on coverage, and this has implications for a national program of EHB (Figure 11-4).

In the course of her work, Ms. Hole-Curry encounters "resistance to public examination" of benefits. She posed an alternate way of thinking about the "real fear" people have that evidence is going to be used "as a way

WA HTA Comparison with Insurer Policies							Reference Sources	
WA HTA			Private Insurer				Medicare	BCBS TEC
Topic	Date	Coverage Decision	Aetna	Group Health	Premera-BS	Regence -BC	NCD	
Upright MRI	May-07	**Not covered**	Less restrictive	No decision	Same	Same	No decision	No decision
Ped Bariatric Surgery <18	Aug-07	**Not covered**	Less restrictive	Less restrictive	Same	Same	n/a	No decision
Ped Bariatric Surgery 18-21		**Conditional**	Same	Same	Less restrictive	Less restrictive	Less restrictive	Same
Lumbar Fusion for DDD	Nov-07	**Conditional**	More restrictive	No decision	Same	Same	No decision	No decision
Discography for DDD	Feb-08	**Not covered**	Less restrictive	Same	No decision	No decision	No decision	No decision
Virtual Colonoscopy (CTC)- Cancer screening	Feb-08	**Not covered**	Same	Same	Same	Same	Same	Less restrictive

Summary Comparison of HTA Decisions and Private Insurers:

- Same as Private (some occur before, some after) 47%
- Private Insurer is Less Restrictive 22%
- Private Insurer is More Restrictive 9%
- Private Insurer Does Not Have Published Policy 18%

FIGURE 11-4 Health Technology Assessment (HTA) program coverage decisions may vary between Washington (WA) state and private insurers.
SOURCE: Hole-Curry, 2011.

to ration care": instead of framing evaluation as taking away choices by only covering interventions with an established evidence base, frame evaluation as aiming to ensure that effective and safe care choices are preserved and interventions that are harmful or without benefit are not covered. For example, premature elective caesarean sections persist despite evidence proving this practice is harmful (Tita et al., 2009), and knee arthroscopy for osteoarthritis continues to be performed despite several high quality studies demonstrating the procedure is no more effective than sham surgery (Kirkley et al., 2008; Moseley et al., 2002).

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12

Lessons from California's Benefit Review Processes

California's Knox-Keene Health Care Service Plan Act of 1975[1] (hereby known as the Knox-Keene Act) regulates health maintenance organizations (HMOs) within the state. Cindy Ehnes, the Director of California's Department of Managed Health Care (DMHC) described the core benefits provided under the Knox-Keene Act as a "prototype" of the services that should be provided as essential health benefits (EHB) under the Patient Protection and Affordable Care Act (ACA). The DMHC provides an "insurance product" with benefits that must be priced and valued in annual contracts. Thus, the department has extensive experience balancing the interrelated issues of benefits, costs, cost sharing, and provider networks. Three panelists from the DMHC—Ms. Ehnes; Maureen McKennan, the Acting Deputy Director for Plan and Provider Relations; and Andrew George, the Assistant Deputy Director of the Help Center—were asked to compare and contrast the Knox-Keene Act's covered benefits with the ACA's EHB and to describe the DMHC's legislatively mandated appeals and external review processes.

Because there is a question of the extent to which state mandates should be included in the EHB, Susan Philip, Director of the California Health Benefits Review Program (CHBRP), discussed CHBRP's process for reviewing and evaluating benefit mandates proposed by the California legislature. Anthony Wright, Executive Director of Health Access California, then relayed consumer concerns about the fine print of insurance contracts and fear of personal bankruptcy, as well as consumer perspectives on benefit design and the coverage review processes presented by other panelists.

PRESENTATION BY MS. CINDY EHNES, MS. MAUREEN MCKENNAN, AND MR. ANDREW GEORGE, CALIFORNIA DEPARTMENT OF MANAGED HEALTH CARE (DMHC)

Ms. McKennan began by explaining that California is a "dual regulatory state" in that health plans are regulated by the DMHC under the Knox-Keene Act, and other forms of health insurance are regulated by the Department of Insurance under the state's insurance code. She said this distinction means that DMHC regulates all of the HMOs and some of the preferred provider organizations (PPOs) products offered in the state. These products offer comprehensive benefits (hospital, medical, and surgical services) and must include a set of basic benefits specified in the Knox-Keene Act. In addition to the eight basic benefits included in Table 12-1, plans regulated by the DMHC must also cover separately statutorily mandated benefits including mental health services, cervi-

[1] Knox-Keene Health Care Service Plan Act of 1975. California Health and Safety Code, Chapter 2.2 § 1340.

TABLE 12-1 The Covered Benefits, Mandatory Benefits, and Optional Benefits for Plans Governed by California's Knox-Keene Act

Covered Basic Health Care Services Benefits Under Knox-Keene[a]	Examples of 44 Statutorily Mandated Benefits	Optional Benefits
• Hospital inpatient services* • Physician services* • Outpatient/ambulatory care* • Lab and radiology* • Home health • Preventive health services* • Emergency services* (including ambulance and out-of-area coverage) • Hospice (only for group coverage)	• Mental health parity* for severe mental illness and serious emotional disturbance of a child [1374.72][b] • Various cancer screenings such as cervical and prostate cancer screenings and mammography [1367.665, 1367.66, 1367.64, 1367.65] • Testing for Expanded Alpha Feto Protein (AFP) (prenatal testing) [1367.54] • Prohibits plans from limiting inpatient hospital care following childbirth to less than 48 hours (vaginal delivery) and 96 hours (caesarean section) [1367.62] • HIV testing [1367.68]	• Outpatient prescription drugs* [1342.7, rule 1300.67.24][b] • Chiropractic services • Dental care • Hearing aids

NOTE: The asterisk (*) indicates similar benefits are also listed as categories under Section 1302(b) of the ACA. In addition to the above-starred categories, the ACA specifies maternity and newborn care, rehabilitative and habilitative services, chronic disease management, and pediatric services including oral and vision care. Maternal and newborn care, and rehabilitation/habilitation are not listed separately in Knox-Keene but considered subsumed under hospital, ambulatory, and physician services. Additionally, while prescription coverage is an optional benefit in California (but usually purchased as a rider), it is required under the ACA. The preventive health services provision under Knox-Keene includes vision screening and oral health risk assessment for children.

[a] Knox-Keene Act Section 1345 (b); Section 1367 (i), rule 1300.67.

[b] Brackets include Knox-Keene Act sections.

SOURCE: DMHC, 2011.

cal cancer screenings, and HIV testing. Ms. Ehnes clarified that many of these statutorily mandated benefits fall under the Knox-Keene covered benefits, but because there were disputes over whether they were covered, the state legislature took the added step of explicating their inclusion in benefit plans.

Grievance and Appeals Processes

Ms. McKennan proceeded to detail the DMHC's policies and processes for addressing grievances and appeals when consumers seek care that has been denied. The Knox-Keene Act describes what Ms. McKennan called "the how, the what, and the when for the plan to respond to these grievances"[2]:

- For standard grievances, the plan has to respond within 30 days, whereas for urgent grievances, the plan has to respond within three days.
- The plan needs to send the enrollee a written response that includes a clear and concise explanation of the denial, including the clinical reasons, the criteria, or the guidelines that were used in making the determination.
- For coverage denials, the plan needs to cite a specific portion of the evidence of coverage or plan contract.
- When the plan denies a grievance, the plan needs to inform the enrollee of the right to appeal to the DMHC.

Unless an earlier review by the DMHC is warranted, enrollees must first exhaust the plan's internal grievance and appeals processes before appealing to the DMHC, but enrollees are not limited in the content and issues about which they can appeal, including access to care and denial of service. Once these grievances and appeals reach

[2] § 1368.

the DMHC, the Department has two processes for conducting an external review: the standard complaint process and independent medical review (IMR).

Mr. George clarified that neither review process occurs automatically after a plan has completed its internal grievance process; these processes are "initiated by the enrollee." Ms. Ehnes described this as one of her principal concerns as director: "They have to raise the complaint. So there must be a process where people who do not complain are able to start accessing the advances in science and medicine." This exchange prompted committee chair Dr. Ball to ask whether DMHC knew anything about those enrollees who were denied coverage but did not file a grievance. In response, Mr. George noted that DMHC oversees care for 21 million enrollees, and in 2010, 6,800 grievances were filed through the standard complaint process and 1,776 grievances were filed through the IMR process.[3] While DMHC constantly reviews information to look for trends (e.g., a specific insurer frequently denying coverage), internal appeals data are not easily accessible. The DMHC's triennial plan survey could, though, provide insights into these denials; the DMHC's public health and clinical professionals conduct on-site surveys of all licensed plans at least every three years and issue reports to the public that discuss plan performance in the areas of health care accessibility, utilization management, quality improvement, and member grievances/appeals. Ms. Ehnes noted that even a single case can provide clues to what might be a more widespread problem.

Standard Complaint Process

Standard grievances and appeals might involve coverage issues, billing disputes, and enrollment and eligibility determinations. These issues tend to be "easily resolvable" by reviewing the evidence of coverage or plan contracts. When disputes involve both a coverage determination and a health care service question, such as disputes related to reconstructive surgery, oral surgery, and some services for autism, the DMHC is the "final arbiter" on whether the grievance should proceed through the standard complaint process or an IMR.

Independent Medical Review

An IMR is a process by which expert independent medical professionals assess clinical coverage decisions made by an insurance company. IMRs are conducted when a grievance or appeal relates to a disputed health care service, and the decision in the case is binding on the health insurer. In 2010, the most common grievances by type of treatment involved pharmaceutical benefits (20 percent of all IMRs) and mental health benefits (11 percent of all IMRs) (see Table 12-2). Ms. McKennan informed the committee that the most common pharmaceutical grievances related to Botox treatment for migraines and growth hormone therapy for idiopathic short stature; the most common mental health grievances related to treatment for autism spectrum disorders and inpatient treatment for substance abuse and eating disorders.

Table 12-3 describes the major classes and quantity of grievances filed in 2010 and their disposition. In 2010, 661 decisions (out of 1,452 grievances that proceeded through the IMR process) were in favor of the enrollee; for each of these, the plan was required to authorize the treatment within five days of receiving the decision. Regardless of the outcome, the IMR decision is given to both the enrollee and the plan and these redacted decisions are posted on the DMHC website.[4]

Ms. Ehnes described the additional 324 cases reversed by the plans themselves, before external review was initiated upon being notified that an IMR was filed, as "very significant." She said that when the DMHC sees a plan reversing "a lot of decisions," the department utilizes its enforcement mechanisms to "drill down" and ensure the plan is not "denying things and just pro forma waiting for someone to complain." Frequent reversals may indicate that a plan is making denials despite evidence in favor of the service. In response to a question from committee member Dr. Ho, Mr. George confirmed that these reversals did not tend to result from the plan reconsidering new

[3] The California Department of Health Insurance has authority over non-managed care related appeals; during 2010, its IMR program had 428 reviews (California Insurance Code, Section 10169).

[4] To review these decisions, go to the DMHC website: http://www.hmohelp.ca.gov/dmhc_consumer/pc/pc_imrdec.aspx (accessed April 26, 2011).

TABLE 12-2 Independent Medical Reviews (IMRs) by Treatment 2008-2010

Treatment	2008 (%)	2009 (%)	2010 (%)
Acute Medical Services Outpatient	10	5	5
Autism Related	2	2	6
Cancer Care	5	6	5
Diagnostic Imaging & Screening	2	2	3
Durable Medical Equipment	9	8	7
Electrical Thermal Radio Frequency Interventions	2	3	4
General Surgical Procedures	5	5	5
Mental Health	8	10	11
Orthopedic Procedure	5	5	5
Pharmacy	24	22	20
Reconstructive/Plastic Surgery Procedure Rehab/Outpatient	3	2	3

SOURCE: DMHC, 2011.

TABLE 12-3 Comparison of 2010 Independent Medical Review (IMR) Results

Types of Reviews	Upheld by Review Number (%)	Overturned by Review Number (%)	Reversed by Plan Before Review Number (%)	Qualified IMRs (Total Number)
Medical Necessity	467 (41%)	452 (40%)	222 (19%)	1,141
Experimental and Investigational	269 (51%)	195 (37%)	67 (13%)	531
Emergency Room Reimbursement	55 (53%)	14 (13%)	35 (34%)	104
TOTALS	**791**	**661**	**324**	**1,776**

SOURCE: DMHC, 2011.

clinical information, as most of this new information should have already been brought to light through the plan's internal review process.

Ms. McKennan further discussed the three categories of IMRs in Table 12-3: those that review medical necessity determinations, those related to experimental and investigational therapies, and those that address reimbursement for emergency room (ER) visits.

Medical Necessity

Medical necessity IMRs occur when a provider recommends a health care service and the plan denies the service throughout the plan's internal appeals process on the grounds that it is medical unnecessary. The Independent Review Organization (IRO) selects an expert reviewer who considers all pertinent medical records, provider reports, and other relevant information. The reviewer decides whether the disputed service is medically necessary based on specific medical needs and any of the following: peer-reviewed scientific and medical evidence, nationally recognized professional standards, expert opinion, generally accepted standards of medical practice, or treatments that are likely to provide a benefit compared to other available treatments.

Experimental and Investigational (E&I) Therapies

For a grievance to be addressed through an experimental and investigational (E&I) IMR, the enrollee needs to have a life threatening or seriously debilitating disease or condition. If a plan denies coverage for an E&I treatment, the plan must notify the enrollee within five days of the right to pursue IMR. In these cases, the enrollee

does not need to go through the plan's internal grievance and appeals process but can instead proceed directly to the external IMR process.

Ms. McKennan described the E&I process as "a little bit easier than the medical necessity standard of review" as it principally aims to address whether or not the requested therapy is likely to be more beneficial than any other available standard therapy. To do so, a panel of three independent experts considers the enrollee's specific medical condition, relevant documents, and medical and scientific evidence.

The E&I IMR process has resulted in some changes to benefit packages by driving standards of care for new and evolving therapies. This translation of benefits from being experimental into practice occurs when the DMHC "sees a pattern, either from a particular insurer or related to a particular form of therapy." For example, when E&I denials related to oncotype testing for breast cancer were repeatedly being overturned by the IMR, Ms. Ehnes said DMHC "went back to the plan and to other plans to say this is now really accepted practice, and it needs to be translated into your review process so that we aren't continuing to get denials."

Denial of Emergency Room Reimbursement

The third type of IMR is used when an enrollee received emergency services that a provider thought was medically necessary but the health plan denied reimbursement. In these cases, the IMR reviewer applies a "prudent layperson" standard to determine whether the enrollee "acted reasonably in seeking emergency services."

Grievances and Appeals Under the ACA

ACA requires plans to have internal and external grievance and appeals processes.[5] Until further regulatory guidance is provided, the HHS has deemed most states' external review processes as compliant with the interim regulations. Ms. Ehnes said the forthcoming regulatory guidance is expected to provide specific requirements for the external review process and detail ways in which states can eliminate barriers to filing a grievance or appeal. Ms. McKennan said this latter issue, in particular, is not a concern in California as enrollees can complain to the DMHC about "any kind of subject they wish" and there are no barriers to filing a complaint (except, in some instances, that the enrollee must first proceed through the plan's internal grievance and appeals process). Table 12-4 provides a side-by-side comparison of the appeals process under both the Knox-Keene Act and the ACA.

Broad vs. Narrow Definitions of EHB

Ms. McKennan concluded by exploring ways in which the committee might learn from California's experiences with benefit design. She said that while the ACA requires the Secretary to define EHB, it does not specify whether the Secretary should adopt "broad or specific regulations" to define these benefits. DMHC's experiences indicate that while broad categories allow for flexibility as new diagnoses and treatments become professionally recognized standards, these broad categories, Ms. McKennan said, may create uncertainty about whether a treatment must be covered by a plan. This latter concern has resulted in numerous mandated benefits (see the center column in Table 12-1). The need for clarification given the "broad" nature of the Knox-Keene covered benefits was highlighted by an exchange between committee member Dr. Wadhwa and Ms. Ehnes: while the Knox-Keene Act does not specifically list maternity and newborn care, such coverage is considered to be part of the basic health care services. Ms. McKennan explained that more defined benefits eliminate this uncertainty by providing clarity about whether a particular service is covered, but may increase the risk that something not specifically listed will be considered excluded.

Ms. Ehnes said that one of the challenges DMHC faces is when a new product or service "comes on the scene," coverage policies may not explicitly state whether this is or is not covered. While the insurance products are contracted on an annual basis and thus provide opportunity to include these new treatments, the continual

[5] Several regulations and guidance on internal appeals and external review processes have been issued. For more information go to: http://cciio.cms.gov/resources/regulations/index.html#ea (accessed August 17, 2011).

TABLE 12-4 Comparison of Grievance and Appeals Processes Under the Knox-Keene Act and the ACA

	Knox-Keene Act	ACA
Internal claims response time for non-urgent cases	5 days	15 days with 15 day extension possible
Internal claims response time for urgent cases	3 days	24 hours
Internal appeals response time for non-urgent cases	30 days for both pre/post-service requests	30 days for pre-service requests/60 days for post-service requests
External review response time for non-urgent cases	30 days	45 days
Claimant's right to present evidence	Does not address (enrollees are allowed to submit additional information by writing to the DMHC)	Expressly allowed (unclear if the regulation would allow evidence be presented through an administrative hearing/testimony)
Cost to enrollee for IMR (Independent Medical Review)	Free (paid by plan)	$25 nominal fee (balance paid by plan)

SOURCE: DMHC, 2011.

addition of new products and services "potentially creates some issues related to the pricing of that package and the year-to-year sustainability and affordability."

Because the Knox-Keene Act does not define medical necessity, enrollees can more easily make the case for covered services. This open-ended "definition" of medical necessity means that an IMR may determine if a particular enrollee must be given a particular treatment. This standard requires the reviewers to consider the evidence base for a treatment labeled "experimental" and authorize the treatment if it might be better than current alternative treatment options. While noble in purpose, in practice it means that few treatments will not meet this very minimum threshold for evidence, reducing the notion of scientific rigor. For instance, disputes regularly arise over coverage of applied behavioral analysis (ABA) for autism; plans assert that this is an educational treatment, whereas enrollees maintain it is a medical service. Insurers have traditionally set definable and predictable parameters to exclude coverage of non-medical services. Furthermore, she pointed out that habilitative services differ from rehabilitative services in that they do not serve to improve the patient to a pre-illness or injury state, and therefore, do not always have a clearly defined endpoint in either time or scope of services. Without some limitations, these services can substantially increase costs and lead to unaffordability and adverse selection in the insurance market. Ms. Ehnes described medical necessity determinations for autism treatments as "enormously difficult." As HHS considers medical necessity and standards of evidence, Ms. Ehnes advised it to consider "providing clarity on whether a service such as ABA should be covered as an essential health benefit," and if there is a sufficiently rigorous evidence basis for it at this time.

PRESENTATION BY MS. SUSAN PHILIP, CALIFORNIA HEALTH BENEFITS REVIEW PROGRAM (CHBRP)

Ms. Philip introduced CHBRP before discussing how her organization evaluates proposed benefit mandates and sharing insights she has gleaned from the evaluation process. Established in 2002 by the state legislature, CHBRP's researchers (i.e., faculty and researchers from the University of California, San Francisco, and the University of California, San Diego, and program staff) analyze the medical effectiveness, cost, and public health impact of proposed state legislative health insurance benefit mandates or repeals and provide this independent, evidence-based information to the legislature. To ensure timely information, CHBRP has only 60 days to complete its analysis. The findings do not include any policy recommendations; rather, Ms. Philip said, CHBRP provides its report, and legislators use the information to determine whether the mandate is a "policy worth pursuing."

Of all the types of benefit mandates CHBRP evaluates, Ms. Philip described two, in particular, that are relevant to the committee's work: mandates that require coverage for a bundle of services associated with screening,

diagnosis, or treatment of a condition or disease (e.g., a bill to require coverage for services associated with pregnancy, including prenatal care, labor and delivery, and postpartum care) and mandates that require coverage for a specific service, item, drug, or procedure (e.g., hearing aids for children, coverage for the human papillomavirus [HPV] vaccine). More than 20 million Californians are potentially affected by these proposed benefit mandates.

Evaluation Criteria

CHBRP uses three criteria to evaluate proposed mandates—medical effectiveness, cost impact, and public health impact—and relies on a "hierarchy of evidence" to determine the medical effectiveness of the potentially mandated service.

Cost impact concerns the marginal cost of the mandate. CHBRP does not examine the cost of adopting a new technology or of having the benefit being newly covered throughout the entire California health care system. Rather, researchers examine the marginal or incremental impact, including changes in health care expenditures, premiums, and out-of-pocket costs. This marginal impact analysis ensures CHBRP does not over- or underestimate the cost of the mandate.

Similarly, using measures such as morbidity, mortality, disparities, and the economic burden of illness, CHBRP's public health impact analysis estimates the marginal impact of the proposed mandate on the health and productivity of Californians. For example, if there is strong evidence that a particular technology is effective, but the research finds that the insured population already has coverage and there would be no change in utilization, then, Ms. Philip said, "we might say there's no public health impact attributed to the bill." However, if evidence shows the technology is effective and that more Californians being covered would increase utilization, then CHBRP estimates a positive public health impact. Though not always possible, CHBRP attempts to quantify these public health impacts; for example, researchers quantified school absenteeism due to asthma.

Analysis of Repeal Bills

In 2010, a bill introduced in the California legislature would have permitted out-of-state carriers to sell insurance in California without being subject to existing state mandates.[6] This proposal, Ms. Philip said, would have amounted to a repeal of all 44 mandates then required by California law by "allowing carriers to develop, market, and sell products previously prohibited in the market." This issue, she said, is "of particular relevance to the IOM committee." To evaluate the bill, CHBRP performed an "opposite analysis" to see what the reduction in cost would be if the 44 mandates were taken away.

Assessing cost impact was "definitely a challenge," Ms. Philip said, because researchers had little data to anticipate how the market would respond to plans that did not offer such comprehensive coverage. CHBRP developed "prototype" plans based on a review of limited benefit plans in other states. Using these prototypes, researchers developed scenarios of cost reductions and "take-up rates" if the prototypes were available in California.

Assuming plans in the market still offered the basic health care services mandated by California's Knox-Keene Act, researchers determined there would be a 2 to 5 percent cost reduction in the absence of the 44 mandates (CHBRP, 2007, 2010). Stated differently, Ms. Philip said, the mandates add 2 to 5 percent to insurance premiums. Committee member Dr. David Guzick pointed out that this estimate varies significantly from the estimates provided by a previous panel (Chapter 3, Figure 3-1 describes Ms. Malooley's estimate that 69 state mandates in Rhode Island raise premiums by more than 34 percent), which prompted Ms. Philip to reiterate that CHBRP studies the *marginal* cost of the mandates whereas other studies, she said, "actually look at the cost of the benefit as a whole as opposed to looking at the marginal impact of the requirement."[7] In other words, removing all mandates would not mean that plans would drop all coverage since there is considerable overlap with basic health care services and since the market may continue to demand the benefit or service.

[6] California Assembly Committee on Health AB 1904: Out-of-State Carriers.

[7] The CHBRP analysis of Assembly Bill 1214 strictly examines benefit mandates, vs. mandates on process or eligibility.

In response to an inquiry from committee member Mr. Schaeffer, Ms. Philip described the potential impact on public health and the potential for adverse selection resulting from limited benefit plans:

- While the state mandates often overlapped with the Knox-Keene Act's covered services, the mandates tended to go into "further detail" by requiring coverage of mastectomy, for example, rather than just coverage of breast cancer treatment;
- About half of the mandates had a "strong" evidence base—that is, had clear and convincing or a preponderance of evidence of the effectiveness of the mandated benefit or service;
- Approximately one-third of the mandates did not have a "preponderance of evidence;" and
- A "small minority" of the mandates had evidence that the mandated benefit is ineffective or associated with potential adverse effects (CHBRP, 2010).

Evaluation and Research Needs

Ms. Philip suggested that information on fiscal impacts, long-term impacts, and comparative effectiveness are essential for the legislature to thoroughly evaluate a bill, but that providing these analyses is often quite challenging. Given states' budget crises, states particularly need "reliable fiscal impact analysis" by independent parties to gauge the states' fiscal liability if existing mandates "are considered to exceed the EHB floor." Reliable fiscal impact analysis also helps decision makers weigh the utility of the benefit with the potential tradeoffs. Recently, for instance, California legislators used CHBRP's cost-effectiveness analysis to weigh the merits of mandated tobacco cessation services. During a public discussion hearing of the Assembly Committee on Health, legislators cited CHBRP's report and its summary of cost-effectiveness research as a reason for voting in favor of the bill (State of California, 2010).

Evaluations of proposed benefits should, where feasible, include a long-term impact analysis. Though doing so is challenging, CHBRP summarizes the available cost-effectiveness analysis to present the effect of a mandate in terms of quality adjusted life years. Ms. Philip pointed out that such analysis allows policy makers to consider the long-term societal impacts and ramifications of their decisions. Long-term analysis that examines effects over 10 to 30 years is particularly important when evaluating benefits for preventive services or chronic care management.

For assessing specific benefits, Ms. Philip believes comparative effectiveness research (CER) would be very valuable in determining which benefits to include in an EHB package. Recently, for instance, CHBRP analyzed a bill that would require parity in cost sharing for anticancer medications (CHBRP, 2009a). Under the bill, co-pays for intravenous injectable drugs obtained in a physician's office would have had to be "on par" with co-pays for oral anticancer medications.[8] In the absence of reliable CER, CHBRP was unable to conduct medical effectiveness analysis on the comparative effects of benefit design on access to anticancer medication.

Lessons Learned

Ms. Philip concluded her presentation by sharing some of the feedback CHBRP has received from policy makers, stakeholders, and researchers, and by providing her own insights. First, the independence of the evaluation process is important, and the process must allow for stakeholder input. The transparency of CHBRP's processes has helped improve its methods while enhancing the credibility and reliability of its reports. Second, the reports are actually used by policy makers, she said, because they "show up" in time for the deliberation process. Third, the analysis must be clearly communicated to lay audiences; translation of technical research findings into "readable" text must be a "built-in" part of the evaluation process.

Ms. Philip concluded by emphasizing that while somewhat unsatisfying, a lack of evidence can be just as important as other research findings. If there is not enough evidence to actually draw a conclusion, she said, then it is important to highlight the lack of a strong evidence base. In CHBRP's experience, when a mandated benefit

[8] California Assembly Committee on Health Bill 161: Health care coverage: Chemotherapy treatment.

lacked a strong evidence base, the bill is typically not pursued either because the author decides not to pursue the bill or the legislature fails to pass the bill (CHBRP, 2009b).

PRESENTATION BY MR. ANTHONY WRIGHT, HEALTH ACCESS CALIFORNIA

In its 25-year history, Health Access California has become, Mr. Wright said, "the statewide health care consumer advocacy coalition," working on developing and passing specific consumer protections and broad health reforms at the state level. The organization was actively involved in the creation of the DMHC and its IMR process. Mr. Wright expressed his support for both the DMHC's IMR process and the CHBRP's benefit review process, calling these "balanced processes that are iterative, allow for the evolution of benefit design, and have consumer-based criteria as part of their processes."

With its state partners, Health Access has "grappled" with issues around health care coverage and the tradeoffs related to affordability. While recognizing the need to balance affordability and the comprehensiveness of benefits, Mr. Wright expressed that "a cheap premium is always attractive, but even cheap junk is still junk."

A "Layperson's Definition of Coverage"

As part of several health reform efforts, including one by Governor Arnold Schwarzenegger in 2008 that eventually stalled (State of California, 2008), Health Access participated in privately-funded focus groups and other opinion research projects. During this research, Mr. Wright said, consumers and small businesses were asked for their opinions about what constitutes basic health benefits. The list, he said, was "remarkably consistent" from group to group and included physician services, hospitalization and ambulatory care, diagnostic laboratory tests, diagnostic and therapeutic radiology, home health services, preventive health services, emergency health care services, hospice care, prescription drug coverage, and mental health parity. This "layperson's definition of coverage," he said, "includes an expectation of coverage for basic services." These basic benefits were regarded as those benefits covered by most employer-based plans in California.

"The Fear of the Fine Print" and Bankruptcy

Mr. Wright said that one of the things he most often hears from consumers and patients is a "fundamental fear of the fine print." Exclusions, loopholes, and caveats are of great concern to patients as they worry about not having care "when they most need it." The ACA tries to mitigate these fears with strict regulation of rescissions,[9] no denials for pre-existing conditions, a standard on medical loss ratios,[10] out-of-pocket maximums, and an end to lifetime and annual limits for EHB—these policies address the core problem of patients not feeling a "sense of security," he said.

Mr. Wright described the ACA as being "as much about economic security as it is about health care coverage" for patients. During the health reform debate, for instance, consumers rallied (via Facebook® and Twitter®) behind the notion that "no one should go broke because they get sick." However, he said, people buy coverage based on the above-discussed "layperson's definition of coverage," and therefore, when there are holes in the benefits, people are left in a "financial trap."

Mr. Wright proceeded to elaborate on California's Knox-Keene Act. Because of this law, he said, "most health coverage sold in California has a much better standard for a basic benefit package" than in other states. Under the Knox-Keene Act, the DMHC regulates approximately 80 percent of coverage in California (an estimated

[9] Under Section 1001 of the ACA, adding § 2712 to the Public Health Service Act, plans or issuers are generally prohibited from cancelling or discontinuing coverage unless there is fraud or an individual makes an intentional misrepresentation of material fact. A rescission is defined as "a cancellation or discontinuance of coverage that has a retroactive effect, except to the extent attributable to a failure to pay timely premiums towards coverage" (DOL, 2011).

[10] Patient Protection and Affordable Care Act of 2010 as amended. Public Law 111-148 § 10101(f), adding § 2718 to the Public Health Service Act, 111th Cong., 2d sess.

17 to 18 million covered lives). A low standard for minimum essential benefits could undermine the Knox-Keene standard provided to a majority of Californians.

The remaining 10-20 percent of coverage is regulated by the California Department of Insurance, where, Mr. Wright said, there is not a basic standard of included services. Some of these plans, for instance, may cover hospitalization for the first night, but not the second night, or vice versa. Some limit prescription drugs coverage to only generics and do not cover even medically necessary brand-name drugs without a generic equivalent. These plans, he said, do not have "an appropriate mechanism for setting essential benefits."

Mr. Wright used two examples to show how even consumers who "do the right thing and voluntarily purchase health insurance" regulated by the Department of Insurance can see their "financial security destroyed by the fine print":

- Susan Braig, a self-employed graphic designer, bought what she thought was catastrophic coverage; when she was diagnosed with breast cancer, virtually none of her care was covered because her treatments were provided on an outpatient basis and she had purchased a hospital-only plan. She ended up uninsurable and with tens of thousands of dollars in medical debt.
- Laura Burwell, a small business owner, thought she was purchasing private nongroup coverage that was as comprehensive as the coverage offered by her previous employer. When she was bitten by a rattlesnake in the backyard and taken to a local hospital, her plan did not cover the first and most expensive day in the hospital. Her bill for that first day of care was over $73,000; her insurance covered only $3,000.

Mr. Wright argued that having insurance products with these kinds of loopholes provides no benefit to consumers. Consumers cannot and should not be expected to anticipate needing care for every ailment and "even when plans prominently disclose the holes in their benefits (which many do not), they rely on consumers to have actuarial and medical information to provide context and evaluate risk appropriately." In making an argument that "simplicity matters," Mr. Wright said that a competitive marketplace in which insurers compete on cost and quality rather than on "how confusing the benefit packages are" will be in everyone's best interest.

Consumer Insights on Medical Necessity Determination

The Knox-Keene Act specifies that care recommended by a provider, including out-of-network providers and emergency care, is subject to a determination of medical necessity. If care is disputed, IMR determines whether the disputed service was indeed medically necessary, based on the "specific medical needs of the enrollee."[11] This requirement means that if a diabetic with a broken leg needs physical therapy because of delayed healing due to diabetic complications, the reviewers must take that into account. As a result, allowable medications, length of hospital stays, and specific types of surgical procedures may vary depending on the individual medical needs of the patient. Health Access, Mr. Wright said, supports the consideration of individual medical needs and opposes inclusion of uniform limits of medical necessity on the grounds that specific limits often "short-change persons with disabilities or degenerative conditions." Without specific limits, he said, medical necessity determinations can be more iterative.

Consumer Insights on Benefit Mandates and Exclusions

Mr. Wright stated that Health Access supports some state benefit mandates, including mental health parity and coverage of prenatal and maternity care in the individual market. He cautioned, though, that even as consumer advocates, Health Access does not regularly endorse specific benefit mandates (sometimes proposed by industry to promote specific drugs, devices, or tests). One of the reasons his organization does not always support these mandates, he said, is that once enacted, mandates do not tend to evolve as treatments and evidence change. Health Access supports CHBRP's process to evaluate the marginal cost and public health impact of potential mandates.

[11] California Health and Safety Code, Section 1374.33.

Mr. Wright concluded by stating that exclusions on benefits often "impose costs on public programs and taxpayers" because when frequently used therapies are not covered, public programs "pick up the slack." For example, Medi-Cal covers the cost of durable medical equipment (DME) for some eligible patients if the equipment is not covered by a health plan. The lack of maternity coverage has meant additional government costs in programs like Medi-Cal and Access for Infants and Mothers. Furthermore, Mr. Wright advised the committee that "consideration of affordability must include not just premiums, but the full costs to the patient, including cost sharing due to co-payments, deductibles, and benefits not covered." He reiterated that "you want to give people confidence in their coverage."

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13

Priority Setting and Value-Based Insurance Design

In an ideal world, Somnath Saha said, benefit packages would be designed with only patient care, safety, and effectiveness in mind. In reality, though, states, health insurance plans, and the federal government must also consider cost-effectiveness and affordability. In this panel, Dr. Saha, a practicing physician and volunteer chair of Oregon's Health Services Commission (HSC), and Jeanene Smith, the administrator of the Office for Oregon Health Policy and Research (OHPR), described Oregon's experience in setting priorities when funds are limited. Additionally, they discuss developing value-based insurance design across the public and private sector in Oregon. Jean Fraser, the current chief of the San Mateo County Health System and the former CEO of the San Francisco Health Plan, built on these points by discussing her experience "making hard choices" when developing benefit plans for two California coverage programs.

PRESENTATION BY DR. SOMNATH SAHA, PORTLAND VA MEDICAL CENTER AND THE OREGON HSC

Dr. Saha explained the function of the Oregon HSC and his role as chair. The commission develops the state's health care priorities in the form of a rank-ordered list of health care services. They then "hand" this list to the state legislature, which uses it to develop Medicaid benefits packages. The HSC first began its work in 1989, when the governor and legislature recognized the problem of rising health care costs and determined that in order to maintain the state's Medicaid expansion, it would need to "trim covered services, not trim people" (*The Economist*, 1998). The HSC is now comprised of 12 members, principally generalist physicians—including Dr. Saha, who is a primary care physician at the Portland Veterans Affairs Medical Center—and consumer advocates. Dr. Saha described its role as that of a gardener: the commission oversees a list of prioritized services and "tends the garden" by correcting errors, incorporating new services, and improving prioritization processes.

Developing a Prioritized List of Covered Services

The HSC developed and now maintains a prioritized list of covered services that are "rank-ordered" according to impact on health, treatment effectiveness in improving and promoting health, and public values and priorities. Since the implementation of the rank-ordered list in 1994, the HSC has regularly updated the list and biennially submits it to the legislature, which "draws a line" at which the state stops covering benefits based on the amount the

state can afford for the covered population. This latter decision of where to draw the line is primarily made using actuarial analysis of the cumulative costs of services. Currently, Dr. Saha said, approximately 75 percent of the over 600 lines of condition-treatment pairs are covered (Table 13-1) (Oregon Health Services Commission, 2011).

The HSC's prioritization methodology was "reinvented" in 2006. The HSC first ranks nine categories of care based on healthy life years and impact on suffering, among other criteria. Each category of care is given a weight, ranging from maternity care with a weight of 100 to inconsequential care with a weight of 1 (see Table 13-2). The category list does not mean that all maternity care is prioritized over preventive care; rather, these category rankings are one component in an overall scoring formula. Dr. Saha pointed out that these categories of care are based on Oregon's priorities and not on organ systems or type of provider. As a result of this distinction, dental and mental health care are integrated in the category list. Second, the HSC goes "line by line" and scores each condition and treatment within these categories of care based on eight impact measures: impact on health life years, impact on suffering, population effects beyond the affected patient (e.g., contagious diseases), vulnerability of the population affected, prevention of downstream complications, treatment effectiveness, the need for medical services, and net cost. The comprehensive list of conditions and treatments is built using diagnostic codes and procedure codes (i.e., ICD-9, CPT, and HCPCS [Healthcare Common Procedure Coding System] codes). Thus, a procedure without a CPT code is not included on the list, and prescription drugs and DME apply to many different lines on the list. To address this latter shortcoming, these products are called "ancillary services" and are "blanketly covered for conditions that fall within the covered range of the list." Additionally, the list is used to determine the coverage of treatments only after the necessary diagnostic services establish the condition.

TABLE 13-1 Selected Elements and Rankings from the Oregon Health Services Commission's Prioritized List for Medicaid

Line Number	Examples of Services	Coverage
1	Maternity care	↑
101	Medical treatment of acute lymphocytic leukemia	
201	Surgical treatment of brain hemorrhage	
301	Treatment for rheumatic heart disease	
401	Laser therapy to prevent retinal tear	
501	Treatment for noninflammatory vaginal disorders	
		Covered
		Not Covered
551	Treatment for back pain without neurologic impairment	↓
651	Treatment for calcium deposits	

SOURCE: Oregon Health Services Commission, 2011.

TABLE 13-2 Oregon Health Services Commission's Prioritized Categories of Care and Associated Weights

Ranking	Category of Care	Weight
1	Maternity/newborn care	100
2	Primary and secondary prevention	95
3	Chronic disease management	75
4	Reproductive services	70
5	Comfort care	65
6	Fatal conditions—acute care	40
7	Nonfatal conditions—acute care	20
8	Self-limited conditions	5
9	Inconsequential care	1

SOURCE: Oregon Health Services Commission, 2007.

The HSC uses a mathematical formula to rank health services within these categories. The formula considers the category weight (shown in Table 13-2), the service's total impact score (derived from the set of scaled impact measures), the effectiveness of the service, and the need for the service. An example of its application for Type II diabetes (with a weighting of 75 for chronic disease management) is illustrated in Box 13-1.

Effectiveness, Dr. Saha said, is an important multiplier because you may have a "very high-impact illness," but if a treatment for that illness is ineffective, this multiplier will ensure that the condition-treatment pairing gets a score of 0. Additionally, the "need for service" score ensures the exclusion of services that do not require medical care. Conservative management of a sprained ankle, for example, might be effective but in most cases does not require medical care. The requirement for a service multiplier reduces the priority score for this type of treatment. The HSC only uses net cost, Dr. Saha said, as a "tiebreaker." Although actuaries provide information about what it costs to deliver the service, the HSC has little reliable information about the cost of not delivering the service. Because the commission often found itself "guessing," it excluded net cost from the main formula.

Consumer and Provider Pushback

Dr. Saha acknowledged that consumers and providers have, on occasion, expressed discontent with the priority rankings of specific conditions and treatments. He said, though, that HSC's "straightforward" formula, which was revised from a more complex formula developed in 1991, contributes to the commission's transparency. Because the HSC's process does not include a Delphi panel to review each impact score, he recognized that individuals can and do "quibble with every single line" in terms of whether the commission "got the scoring right." The HSC believes that what it "sacrifices in rigor, it counters with transparency." The scores are available on its website, and an individual or group disagreeing with a score or ranking can present evidence to the HSC as to where and how the scoring for a condition or treatment should change. While the HSC does not change rankings without legislative approval, it does have an open forum to respond to providers, patients, and others who have concerns. The HSC meets several times a year, and the legislature biennially reviews HSC's proposed changes.

BOX 13-1
Example of Oregon's Criteria for Line Item Scoring: Type II Diabetes Mellitus

Impact on Healthy Life Years:	7
Impact on Suffering:	2
Effects on Population:	0
Vulnerability of Population Affected:	2
Effectiveness:	4
Need for Service:	1
Category 3 Weight	75

Net Cost:
Total Score: 3300 → Line: 33

SOURCE: Smith and Saha, 2011.

TABLE 13-3 Oregon's Proposed Value-Based Benefit Tiers Vary in Benefits and Patient Cost Sharing

Service Tier	Examples of Service	Cost Sharing
Value-Based	Routine vaccinations, prenatal care, chronic illness management, smoking cessation treatment	0-5%
Tier 1 (Lines 1-112)	Highly effective care for severe chronic disease and life-threatening illness and injury (e.g., rheumatoid arthritis, heart attack, and low birth weight)	Low
Tier 2 (Lines 113-311)	Effective care of other chronic disease and life-threatening illness and injury (e.g., glaucoma, breast cancer, ADHD)	Moderate
Tier 3 (Lines 312-502)	Effective care for non-life-threatening injury and illness (e.g., ear/sinus infections, herniated disk, reflux, dentures)	High
Tier 4 (Lines 503-679)	Less effective care and care for self-limited illness and minor injury and illness (e.g., chronic back pain, viral sore throat, seasonal allergies, and acne).	Highest

SOURCE: Smith and Saha, 2011.

Using the Prioritized List to Develop EHB

In 2007, during a push for a universal coverage plan in Oregon, the state legislature directed the development of "recommendations for defining a set of essential health services that would be available to all Oregonians under a comprehensive reform plan."[1] The legislature, Dr. Saha said, recommended using Oregon's prioritized list of health services as the basis for developing the state's essential benefits package. To undertake this task, the state formed the Oregon Health Fund Board Benefits Committee that was comprised of health professionals (including Dr. Saha), consumers, and public and private insurers. These diverse parties faced difficulty determining which benefits should be considered "essential," and found it easier to agree on what Dr. Saha called "levels of essentiality." These levels resulted in a tiered benefits package in which higher-priority services have lower cost sharing, one approach to value-based insurance design (VBID). The committee used the prioritized list to create the service tiers. Dr. Saha described the top "value-based tier" as including tests and treatments that are highly effective, low cost, and that the committee wanted to encourage in the population (Table 13-3).

PRESENTATION BY DR. JEANENE SMITH, OFFICE FOR OREGON HEALTH POLICY AND RESEARCH

Since the 2007 development of the value-based benefits package described by Dr. Saha, the state of Oregon has explored how it might implement this package in a state-based health insurance exchange. Dr. Smith described her office's role in developing this option. The OHPR is the policy office within the Oregon Health Authority (OHA), which includes the state's Medicaid and state employee programs, the Oregon Educators' Benefit Board, and the state's high-risk pool (a premium subsidy program). Thus, the OHA has influence over 850,000 covered lives (approximately 30 percent of the state's population), and the cost of covering these individuals plays a large role in state budget discussions. To address rising costs, the OHA aims to use value-based benefit design for these state-covered programs, said Dr. Smith, as well as promote its use in the private sector.

A Hypothetical Example of Oregon's Proposed Insurance Exchange

To illustrate how the program could work, Dr. Smith cited the fictional example of Robert, a single male earning $20,000 per year (Box 13-2). His income is just above Medicaid eligibility, but when an insurance exchange exists in the state, he could purchase insurance through the exchange and get tax credits to assist with his premium. If he chose a Patient Protection and Affordable Care Act (ACA) "silver-level plan" that was based on the value-

[1] Healthy Oregon Act (2007).

BOX 13-2
Hypothetical Example of Costs and Benefits Under a Silver-Level Plan

Robert is single, earns $20,000 per year.

- He purchases insurance through an insurance exchange.
- He will get tax credits to assist with his premium.
- He chooses value-based insurance design (VBID) with 10%/30%/50%/70% tiered co-insurance.
- His deductible is $300; out of pocket max is $1,600—amounts limited due to income level.
- Plan uses evidence-based formulary for medications:
  - $10 for generic,
  - $30 for preferred, and
  - 50% for nonpreferred.

SOURCE: Smith and Saha, 2011.

based insurance design (VBID) model, he would have certain benefits with no cost sharing and variable cost sharing for others. Based on his income level, his deductible would be $300 and his out-of-pocket (OOP) maximum would be $1,600. If Robert had Type 2 diabetes, under his silver-level plan, his insulin, eye exams, and supplies would be covered with little or no cost sharing. If his doctor found a diabetic foot ulcer and referred Robert to a surgeon for an antibiotic and surgical treatment, these services would be covered under tier 1. Robert would have a $10 co-pay for the antibiotic and a 10 percent co-insurance for the surgical procedure. Robert's total OOP cost for his diabetic ulcer would be $470, half of what he would pay had he been insured by a typical employer plan in the state. Under a typical commercial plan, his OOP costs would be $810 plus the cost of exams, insulin, and supplies. Thus, the VBID in the insurance exchange would "drive incentives for the patient to get the care they need," while creating barriers that help patients and payers "avoid marginally effective care," she said. For now, though, the exchange is not yet operational, but the VBID could be used by the OHA's current lines of coverage or by other purchasers of benefits.

Actuarial Estimates for Bending the Cost Curve

Actuaries used information from approximately 100,000 covered lives under Oregon Medicaid and the Oregon Educators' Board plan to price the silver-level plan described by Dr. Smith. The actuaries used "judgment, rules of thumb, and many assumptions," she said, to "tease out" the first estimates of the cost implications of tiered, evidence-based benefit design; initial analysis suggests that a 3 to 5 percent premium reduction would be possible compared to a traditional commercial plan. Dr. Saha explained that this reduction is conservative as it did not incorporate estimates of utilization changes based on extra cost sharing for low-priority services. Dr. Santa, a committee member, asked whether the OHPR had explored how many additional people could be covered if costs were reduced by 3 to 5 percent. Dr. Smith noted that because the state is experiencing a 10 to 15 percent cost growth, the magnitude of this reduction is just one way to "bend the trend" and help minimize the need to "cut populations and benefits."

The OHPR is currently developing a more "robust" unit-cost model to allow for modeling reimbursement by tier. This model will allow Dr. Smith and her colleagues to better determine how they could further reduce costs by coupling the tiered benefits with physician payments. For example, could the plans pay providers more for tier 1 services than for marginally effective services in the bottom tier? If the answer were yes, the exchange would be a "two-way street": cost-sharing arrangements would incentivize patients to use value-based services while payment systems would incentivize providers to deliver evidence-based care. When committee member

TABLE 13-4 Oregon Expects Reduced Cost Sharing in Value-Based Tiers to Increase Utilization of Desirable Services

Service Tier	Change in Utilization Due to Cost Sharing
Value-Based	Moderate increase (10-20%)
Tier 1	Modest increase (5-10%)
Tier 2	None
Tier 3	Modest decrease
Tier 4	Moderate decrease
Prescription Drugs	Moderate decrease
Diagnostic Services	Varies
Ambulance/ED	None

SOURCE: Smith and Saha, 2011.

Mr. Schaeffer asked for further details about how the payment portion of this design would change physician behavior, Dr. Smith acknowledged that her department has not yet determined how "exactly that would happen." She said, though, that the plan could pay cardiologists less for those procedures in tiers 3 and 4 and pay them more for procedures in tier 1. Similarly, she said, obstetricians could be paid more for a vaginal delivery than for a full-term elective caesarean-section.

In addition to the cost implications of tiered benefit design, the OHPR has explored the expected utilization offset by changes in cost sharing. As shown in Table 13-4, use of value-based services (those that are highly effective, low cost, and have strong evidence supporting their use) are estimated to increase by 10 to 20 percent. Dr. Smith noted that the analysis assumed ambulance care would be similarly utilized under regular plans and value-based plans, but explained that because the value-based plans would incentivize primary care and care coordination, ambulance and emergency department use would likely decrease. The analysis, though, did not account for these secondary effects.

Focus Group Findings

In late 2010 and early 2011, the OHPR conducted focus groups with insurers, providers, hospitals, employers, and consumer advocates to gauge their perspectives on a value-based benefit package for non-Medicaid participants. Dr. Smith summarized relevant findings:

- Value-based benefits with low or no cost sharing are appealing.
- Tiered benefit plans are complicated and would require a lot of provider and consumer education.
- The value-based plan should have a greater emphasis on wellness.
- One-size-fits-all plans will not satisfy consumers.

While acknowledging that there are challenges associated with evidence-based benefit design, Dr. Smith closed by expressing that a value-based benefit design could be a vision for balancing access with cost and quality. Using such a plan design in the ACA insurance exchanges would be one way to realize that vision.

PRESENTATION BY MS. JEAN FRASER, SAN MATEO COUNTY HEALTH SYSTEM

Before assuming her current role as chief of San Mateo County Health System, Ms. Fraser served as the CEO of the San Francisco Health Plan, where, in conjunction with the San Francisco Department of Public Health, she designed the Healthy San Francisco universal coverage program. Ms. Fraser's experiences with benefit design provide her with ample "on-the-ground" perspectives about making, what she called, "tough decisions." In both her current and former roles she faces the same dilemma: how do we provide as much benefit as possible with

limited funds? She began her presentation by suggesting that the committee faces a similar dilemma as it designs the essential health benefits (EHB), and posed a question for the committee's consideration: "Fundamentally, what you're going to have to decide is what is the goal of the ACA? Is it to cover the most people for most conditions, or is to cover all care for some people?" The committee's answer to this question, she said, would affect San Mateo County Health System and other public indigent care providers across the country because the people who will be "priced out of coverage will end up" getting care from public hospitals and clinics.

Creating Healthy San Francisco

To address the tradeoffs between cost and coverage, the developers of Healthy San Francisco made some "really, really, difficult decisions." First, Ms. Fraser said, they developed a list of exclusions ranging from acupuncture to long-term care and organ transplants. "Yes, these are some very serious things," she said, but these exclusions allow Healthy San Francisco to "cover most people for most things." Furthermore, the plan has a very narrow provider network. When initially implemented, beneficiaries could only get hospital care at San Francisco General Hospital. Even "perfectly legitimate ED [emergency department] visits" were not covered if treatment was received at a different hospital. While the network has expanded since its inception, the provider group is still "extraordinarily narrow," said Ms. Fraser.

While the exclusions and limited provider network impose significant limits, they also allow the program to cover a "limited set of core services," including prevention and treatment for "most medical conditions for tens of thousands of people who did not have coverage before." Thus, the "choice" the developers made in benefit design "was not between the perfect and the good. It was nothing or something," she said.

Consumer Response to Coverage Limits

Ms. Fraser believes the committee's task is "one of the most important decisions regarding whether the ACA is going to be successful or not," and that an important component of success will be getting stakeholder buy-in on the design of the EHB. She acknowledged that at the outset of implementing Healthy San Francisco, she was concerned that the limits she previously described would make people believe the program did not provide value and would undermine confidence in the plan's mission. Once the plan was unveiled, though, she was surprised that the plan's limits were "accepted almost without objection." While some individuals were unhappy and wanted more benefits, fundamentally, she said, people were happy that coverage was being extended to a previously uninsured population.

She noted that one of the keys to public acceptance of these limitations was that the program was transparent about them by providing a straightforward explanation of the coverage. "There really isn't any fine print." She advised the committee to consider the importance of simplicity over detail because such simplicity and transparency will foster public acceptance.

Making Tough Decisions

In Ms. Fraser's current role, she continues to face complex coverage decisions. She cited a recent coverage determination to highlight the tough decisions faced by public providers. San Mateo County will provide joint replacements when this treatment is the only way to keep a patient out of a wheelchair. The plan does not, however, cover skilled nursing care. Confronted with the issue of what to do with their first patient who was scheduled for hip replacement, Ms. Fraser upheld the decision not to pay for the skilled nursing care. However, she said, the county offered to provide the nursing care at a discounted rate and with a payment plan for the individual, or to teach the family to care for the patient at home. The family elected the latter. While this decision was "tough," it was financially necessary for the county, she said, and ultimately, the medical outcome "was fine," although that might not always be the case.

Lessons Learned

Ms. Fraser closed by sharing some lessons. First, she said, "under-promising so that we can exceed expectations" is crucial. Adding a benefit is much easier than removing one, so if the committee begins with an expansive list of EHB, it will be "virtually impossible to cut it back" should the benefits be found to be unaffordable.

Second, Ms. Fraser expressed strong support for the use of federally funded comparative effectiveness research in benefit decisions. Currently, she said, each provider and each plan is left to figure out these decisions on their own, which results in inconsistent decisions.

To conclude the panel discussion, committee member Mr. Koller asked the panelists whether the committee's time "would best be spent telling the Feds what to do based on your experiences, doing it for the Feds, or telling the Feds what to tell the states to do?" Dr. Saha replied that the latter option would be the most fruitful; whereas Ms. Fraser noted that regardless of whether states do it or the federal government tells the states what to, the committee should develop mechanisms to ensure some level of consistency. She suggested that if the federal government delegates this work to states, states ought to be given the option of following federal rules and/or joining regional consortia to take advantage of economies of scale and data. Also, if states make these decisions, she said, the states should be required to report them to a publicly available central database. The federal government should track results and publish guidance when the evidence becomes clear that certain treatments are more appropriate than others.

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14

Assessing Affordability and the Potential for Underinsurance

Not only uninsured but also underinsured families have high out-of-pocket health care costs and often forego needed care. Jessica Banthin, an economist with the Agency for Healthcare Research and Quality's (AHRQ's) Center for Financing, Access and Cost Trends, and Cathy Schoen, Senior Vice President for Policy, Research, and Evaluation at The Commonwealth Fund, discussed consideration of affordability and underinsurance when designing benefits.

PRESENTATION BY DR. JESSICA BANTHIN, AGENCY FOR HEALTHCARE RESEARCH AND QUALITY (AHRQ)

Dr. Banthin outlined how AHRQ defines high financial burden and used data from the Medical Expenditure Panel Survey (MEPS) to provide information about the population characterized as uninsured. Total out-of-pocket (OOP) financial burden is the sum of a family's OOP expenditures for health care services (e.g., OOP premiums, deductibles, co-pays, and payments for uncovered services) divided by the family's income. Health care service burden is similar except that that the numerator excludes OOP premiums. For privately insured individuals, this latter measure is used to determine underinsurance or "lack of generosity of coverage." In her analysis, Dr. Banthin defines the family as the health insurance eligibility unit (i.e., members of the family who are eligible for family coverage) (Banthin and Bernard, 2006).

Committee member Dr. Chernew asked for further details about how, or if, these measures account for uncovered expenses incurred by individuals. Dr. Banthin clarified that the measures incorporate what "the household chooses to report" and most often capture uncovered expenses. If an individual gets acupuncture that is not covered by his insurance, for instance, he would likely report the expenses he incurred. Similarly, individuals report out-of-pocket expenses for prescription drugs not included in their plan's formulary.

MEPS

MEPS, which is conducted by AHRQ, surveyed a nationally representative sample of approximately 12,000 households and 31,000 people in 2008. The Household Component, in particular, collected detailed information on family income, demographics, health status, chronic conditions, use of and expenditures for health care services,

insurance and employment status, and OOP premiums, among other topics. A separate employer survey collected information on employer premium contributions.

To analyze these data, AHRQ groups services into broad categories: hospital inpatient stays, emergency room visits, outpatient services (i.e., physician and non-physician office-based provider visits), prescribed medicine fills and refills, dental visits, home health care, and supplies and equipment. Dr. Banthin recognized these categories as less detailed than the categories used to analyze claims data, but said the level of detail is a function of the information collected. For instance, MEPS collects information on the reason for a visit, but it does not collect data on the type of provider.

Relevant Findings from MEPS

Next, Dr. Banthin described relevant trends in the 2001 through 2005 MEPS data. For these analyses, she considered individuals who live in families with high total OOP financial burden (i.e., spending 10 percent or more of their income on health care):

- From 2001 through 2005, the percent of individuals in the U.S. nonelderly population who live in families with high financial burden rose from 15.9 percent to 19.1 percent.
- While poor families (under 100 percent of the FPL) are the most likely to have high financial burdens (29 percent of poor families have a high financial burden), one in five low-income (families between 100 and 200 percent of the FPL) and low-middle-income families (families between 200 and 300 percent of the FPL) also reach this level of spending.
- A greater proportion of women ages 50-64 (30 percent) live in a family with a high financial burden than females 18-50 years or males 18-64 years (Banthin, 2011).

In addition to these findings, Dr. Banthin described the financial burden of individuals both with and without employer-sponsored insurance (ESI). Compared with the uninsured and individuals with ESI or public insurance, individuals with private non-group coverage spend significantly more of their income on total OOP expenses (see Figure 14-1). This result, Dr. Banthin said, is because the total OOP spending includes premiums. Comparatively, she said, the uninsured have a lower financial burden because they do not pay premiums and because "they may restrict their health care services in order to avoid having to pay out-of-pocket." However, when Dr. Banthin separated the uninsured into those with a chronic condition and the uninsured without a chronic condition, the uninsured with a chronic condition had a much higher level of burden (27 percent vs. 9 percent, respectively).

Committee member Mr. Michael Abroe noted that Figure 14-1 provides an apt opportunity to compare the private non-group insurance group with the uninsured group; both groups, he pointed out, are likely comprised of families without access to the ESI market. In 2005, 53 percent of families with private non-group insurance had a high financial burden, whereas in this same year, only 15 percent of uninsured families had a high financial burden. Mr. Abroe asked whether this 38 percent difference results from income differences between these two groups, because the uninsured individuals forego care, or because having insurance "induces" increased use of medical care. Dr. Banthin said all of his hypotheses likely factor into the 38 percent difference and cited research that explored the incomes and assets of people who did not have access to the ESI market (Bernard et al., 2009). People who purchased private non-group insurance "tend to have considerably higher wealth, even holding income constant," she said. "But ignoring wealth for a minute, the uninsured definitely have lower incomes on average than the private non-group [individual]," and they use much less care (Bernard et al., 2009).

Committee member Mr. Schaeffer noted that the graph depicted in Figure 14-1 shows a distinct trend: the percent of families with a high financial burden increased from 2001 through 2003 and then decreased or remained steady from 2003 to 2005 (Banthin, 2011). Dr. Banthin commented that these trends are likely the result of trends in the MEPS data, which reflects activity in the economy.

Next, Dr. Banthin explored the distribution of OOP expenses for individuals with a "very high financial burden," which she defined as spending more than 20 percent of family income on OOP health care expenses. In 2003, these individuals spent, on average, $1,528 in OOP expenses; approximately 50 percent was spent on

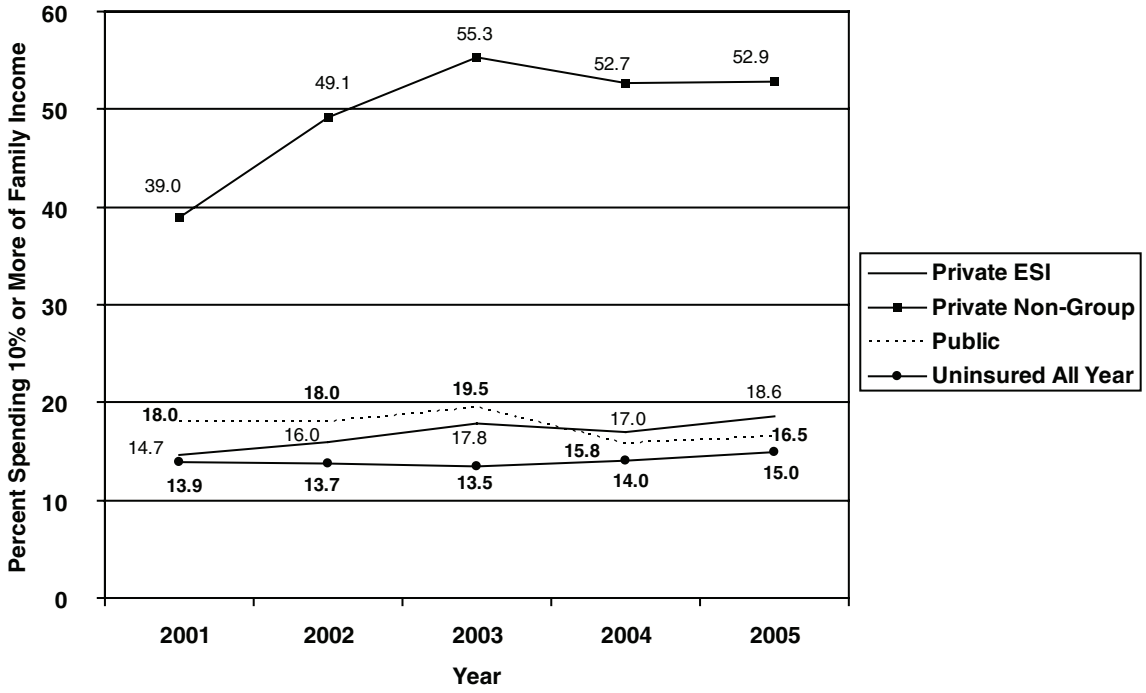

FIGURE 14-1 Percent of families spending 10 percent or more of family income by insurance status.
NOTE: Families with non-group insurance spend more of their family income on health care than uninsured families or families with employer-sponsored insurance (ESI).
SOURCE: Banthin, 2011.

prescription drugs, with the remainder spent on hospital care (8 percent), ambulatory care (23 percent), and all other expenses (18 percent). For families without a very high financial burden (i.e., spending less than 20 percent of family income on OOP health care spending), a smaller percentage of OOP expenses went toward prescription drugs (37 percent). These families spent, on average, $394 OOP—3 percent of which was spent on hospital care, 29 percent on ambulatory care, and 31 percent on other expenditures (Banthin and Bernard, 2006).

PRESENTATION BY MS. CATHY SCHOEN, THE COMMONWEALTH FUND

Ms. Schoen built on Dr. Banthin's comments, describing how The Commonwealth Fund defines underinsurance and suggesting ways the U.S. Department of Health and Human Services (HHS) could design the essential health benefits (EHB) package to protect individuals and families against financial risk. Reiterating a point made by Mr. Wright in a previous panel (see Chapter 12), she described the goal of the Patient Protection and Affordable Care Act (ACA) as being to ensure access to care "with financial protections so that you do not go broke if you are sick." To achieve this goal, one of the challenges that policy makers will face when "moving the uninsured into an insurance category," she said, "is avoiding turning the uninsured into the underinsured."

Defining the Underinsured

The Commonwealth Fund defines the underinsured as families who spend 10 percent or more of their income on medical expenses (very-low-income families are considered underinsured if they spend 5 percent or more of their income on medical expenses). This definition of underinsured is similar to AHRQ's measure of health care service

burden in that it considers OOP medical expenses; however, it does not include premiums. These OOP expenses, Ms. Schoen said, are principally from deductibles, cost sharing for medications, and benefit gaps or limits.

High OOP Costs Affect the Underinsured

An analysis published by Ms. Schoen draws on responses to national surveys sponsored by The Commonwealth Fund. These surveys have tracked the experiences of those identified as "underinsured" since 2003. To accurately reflect OOP expenses that individuals incur while insured, Ms. Schoen and coauthors restricted the analysis to people who have had insurance all year. Consequently, her findings related to the underinsured do not "pick up the millions of people that churn in and out of coverage. Their out-of-pocket expenses might well have come during the three months they were uninsured rather than reflect something about their insurance policy." All of these are classified as uninsured during the year. The analysis reveals that the underinsured are similar to the uninsured in that they often go without care because of costs and have problems paying medical bills.

After publishing an article about the underinsured in *Health Affairs* (Schoen et al., 2008), Ms. Schoen received numerous emails from people describing themselves as underinsured and sharing their stories. Many of these people, she said, told her that they had foregone care because they already had debt from medical expenses. In other work supported by the Fund, patients said, they could not afford additional care and they knew they would be "less than warmly received when they showed up at a physician's office or hospital with unpaid bills." In the analysis, a high proportion of the underinsured and uninsured said they had medical debt and that they used savings and took out loans against their homes to pay medical bills. A high proportion of those reporting medical debt (i.e., they had to pay off medical bills over time) said the expenses occurred while they were insured. These survey findings are supported by other studies on medical debt and bankruptcy, as well as by frequent media accounts (Himmelstein et al., 2005; O'Toole et al., 2004).

As shown in Figure 14-2, both uninsured and underinsured individuals are at high risk of foregoing needed care and of having financial stress related to outstanding medical bills or medical debt (Schoen et al., 2008). These results, she said, have been adjusted for health status and income and show that the "underinsured are much more

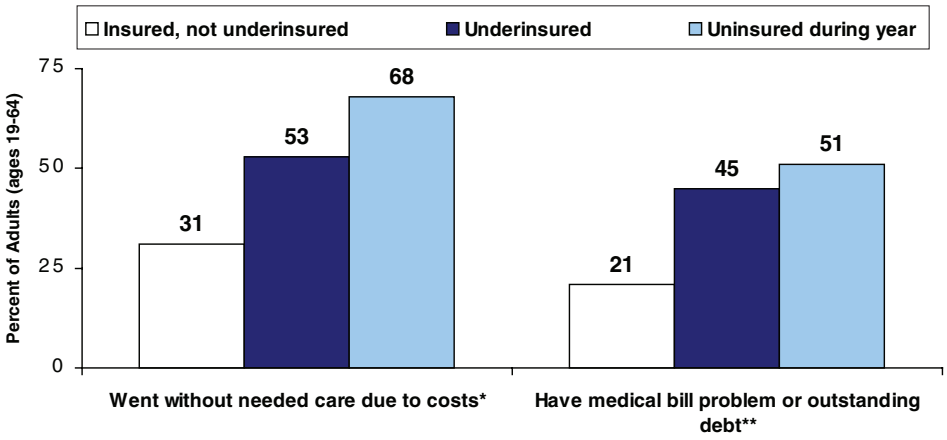

FIGURE 14-2 Underinsured and uninsured adults are at high risk of going without needed care and having financial stress due to medical debt.

*Did not fill prescription; skipped recommended medical test, treatment, or follow-up; had a medical problem but did not visit the doctor or did not get needed specialist care because of cost.

**Had problems paying medical bill; changed way of life to pay medical bills; or contacted by a collection agency for inability to pay medical bills.

SOURCE: Schoen, 2011. Based on analysis published in Schoen et al., 2010.

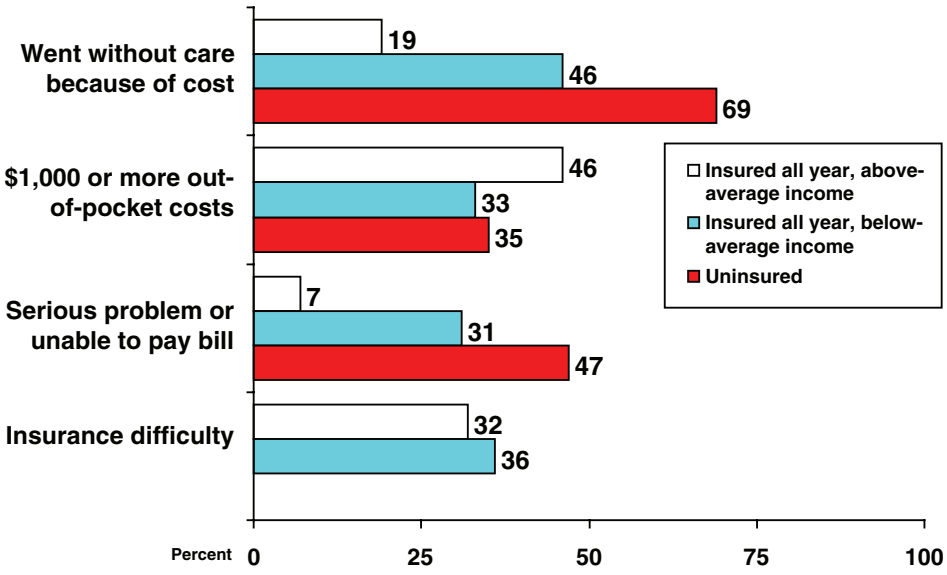

FIGURE 14-3 U.S. adults (under age 65) with below-average income have high out-of-pocket health care costs even when insured.
SOURCE: Schoen, 2011. Based on analysis published in Schoen et al., 2010.

similar to the uninsured than they are to the insured." Dr. Ho, a committee member, noted that the results shown in Figure 14-2 are also "striking" because a significant amount of individuals with insurance forego care (31 percent) and have financial stress due to medical bills (21 percent). Ms. Schoen concurred with this observation and credited some of this foregone care to the burden created by high deductibles.[1] This observation, she said, provides additional reason to be "cognizant" about "where the cost sharing is" in the bronze, silver, gold, and platinum levels mandated by the ACA.

Additionally, how insurers set limits on benefits can seriously impact utilization of necessary care, she said. For example, insured people with capped drug benefits have lower drug utilization and worse control of chronic conditions than insured people without a cap. However, even when benefits are not capped, many individuals still underutilize medications and have less desirable use of medical services (e.g., higher emergency department visits and hospitalizations) (Hsu et al., 2006). Ms. Schoen said research has revealed that when low- or modest-income people face even nominal out-of-pocket costs for essential prescriptions (e.g., insulin for diabetes, statins for hypertension), they often skip refills, which results in higher emergency room use, higher hospital use, and poorer health status (Chernew et al., 2008b; Hsu et al., 2006; Tamblyn et al., 2001). Ms. Schoen used the drug benefit example to reiterate that the aim of the ACA should not only be about providing insurance to the uninsured, but also providing "good insurance" to the underinsured. Fortunately, a lot of employers, she said, have begun thinking about the total cost of care (as opposed to thinking narrowly only about pharmaceutical costs) by moving toward value-based benefits.

Ms. Schoen described the United States as "an outlier on out-of-pocket costs." The country has "much higher cost sharing and deductibles, and many more benefit limits than are typical in other countries" (Schoen et al., 2010). These high OOP costs have a particularly potent impact on when individuals seek care, particularly for families with below-average income, even when the family has insurance (Figure 14-3). In general, studies find

[1] For related studies see Beeuwkes Buntin et al., 2011.

that those with low or modest incomes are particularly sensitive to OOP costs for essential and less essential care (Chernew et al., 2008a; Tamblyn et al., 2001).

Cost-Sharing Provisions in the ACA

The ACA requires a "sliding scale set of premium protections" for families up to 400 percent of the federal poverty level (FPL). Table 14-1 shows The Commonwealth Fund's analysis of cost sharing requirements for the ACA's silver level plan; the amount of the subsidy available in an exchange is tied to the second lowest silver level plan. Ms. Schoen pointed out that the OOP maximum is "substantial," particularly for families under 150 percent of the federal poverty level (FPL), or under 200 percent of poverty. A family making $30,000 per year, for example, would have an OOP maximum of $3,967, which amounts to over 13 percent of their total income. In addition to medical expenses, families could be paying up to 4 percent of their income on health insurance premiums. Families making $35,000 a year would face OOP costs up to 11 percent of their incomes and premiums up to 6 percent of their incomes ($3,967/$35,000). "We don't typically expose people who earn $100,000 or more to spend such high levels of their income," Ms. Schoen said, "but we will for some in the low- and modest-income range."

Considerations in Defining the EHB and Cost Sharing

Ms. Schoen concluded by sharing with the committee some of The Commonwealth Fund's findings gleaned from researching insurance plans both domestically and internationally. First, the EHB, she said, should "be fairly broad in scope without arbitrary limits on the number of physical therapy visits or doctors' visits." If plans are allowed to variably impose such limits, she said, "it is a subtle way of doing risk selection" because the limits could "target people with particular health conditions."

Second, cost sharing should be non-discriminatory by health condition, age, and sex. "Fine print" exclusions, Ms. Schoen said, can "be pretty subtle" and can have the effect of excluding all enrollees with diabetes, for instance, if the plan does not cover insulin.

Third, value-based insurance design offers the opportunity to use cost-sharing requirements to encourage use of valuable services while discouraging use of "discretionary" services. But these benefit decisions, she cautioned, must be evidence-based and transparent (e.g., through public disclosure in a standardized format) so that benefit design is not done with the goal of creating "niche markets for carriers." To lower OOP pharmaceutical costs, for example, Ms. Schoen suggested exploring the exclusion of pharmaceuticals from the general deductible. This way, she said, plans could use a value-based design that encourages use of maintenance drugs.

TABLE 14-1 The Commonwealth Fund's Analysis of Premiums as a Proportion of Income, Out-of-Pocket Maximum, and Actuarial Value for Plans Established Under the ACA

Poverty Threshold 2011	Income Single or Family	Premium as % income, Silver level	Out of pocket maximum	Actuarial value
<133%	S: <$14,484	2%	$1,983	94%
	F: <$29,726		$3,967	
133 to 150%	S: <$16,335	3 to 4%	$1,983	94%
	F: <$33,525		$3,967	
150 to 200%	S: <$21,780	4.0 to 6.3%	$1,983	87%
	F: <$44,700		$3,967	
200 to 250%	S: <$27,225	6.3 to 8.05%	$2,975	73%
	F: <$55,875		$5,950	
250 to 300%	S: <$32,670	8.05 to 9.5%	$2,975	70% if silver
	F: <$67,050		$5,950	
300 to 400%	S: <$43,560	9.5%	$3,967	70% if silver
	F: <$88,200		$7,933	

SOURCE: Schoen, 2011. Based on Collins et al., 2011.

Fourth, Ms. Schoen encouraged standardization of plans and formularies. Now, she said, "there does not seem to be any reason" why one plan has one formulary and another plan has a different formulary. "The more we can get formularies to be rational and more similar to each other, the less we'll drive physicians crazy," she said. One research study found that a physician and her staff spent $68,000 worth of time interacting with plans (Casalino et al., 2009); streamlined billing could save $7 billion annually (Blanchfield et al., 2010). Standardization could have a positive impact on physicians' time and costs; it could also positively affect consumers by allowing them to more easily compare plans.

Finally, Ms. Schoen said that benefits should be designed to encourage "long-term attachment to a primary care provider" by exempting primary care visits from the deductible. Such incentives could encourage patients to have a medical home, visit a primary care provider, and enroll in chronic disease programs.

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Appendix A

Patient Protection and Affordable Care Act, Section 1302

The following excerpt from the law outlines the statutory requirements for the essential health benefits. (See full text of law as amended through May 1, 2010 at http://docs.house.gov/energycommerce/ppacacon.pdf.)

SEC. 1302. ESSENTIAL HEALTH BENEFITS REQUIREMENTS. [42 U.S.C. 18022]
(a) ESSENTIAL HEALTH BENEFITS PACKAGE.—In this title, the term "essential health benefits package" means, with respect to any health plan, coverage that—
(1) provides for the essential health benefits defined by the Secretary under subsection (b);
(2) limits cost-sharing for such coverage in accordance with subsection (c); and
(3) subject to subsection (e), provides either the bronze, silver, gold, or platinum level of coverage described in subsection (d).
(b) ESSENTIAL HEALTH BENEFITS.—
(1) IN GENERAL.—Subject to paragraph (2), the Secretary shall define the essential health benefits, except that such benefits shall include at least the following general categories and the items and services covered within the categories:
(A) Ambulatory patient services.
(B) Emergency services.
(C) Hospitalization.
(D) Maternity and newborn care.
(E) Mental health and substance use disorder services, including behavioral health treatment.
(F) Prescription drugs.
(G) Rehabilitative and habilitative services and devices.
(H) Laboratory services.
(I) Preventive and wellness services and chronic disease management.
(J) Pediatric services, including oral and vision care.
(2) LIMITATION.—
(A) IN GENERAL.—The Secretary shall ensure that the scope of the essential health benefits under paragraph (1) is equal to the scope of benefits provided under a typical employer plan, as determined by the Secretary. To inform this determination, the Secretary of Labor shall conduct a survey of employer-sponsored coverage to determine

the benefits typically covered by employers, including multiemployer plans, and provide a report on such survey to the Secretary.
(B) CERTIFICATION.—In defining the essential health benefits described in paragraph (1), and in revising the benefits under paragraph (4)(H), the Secretary shall submit a report to the appropriate committees of Congress containing a certification from the Chief Actuary of the Centers for Medicare & Medicaid Services that such essential health benefits meet the limitation described in paragraph (2).
(3) NOTICE AND HEARING.—In defining the essential health benefits described in paragraph (1), and in revising the benefits under paragraph (4)(H), the Secretary shall provide notice and an opportunity for public comment.
(4) REQUIRED ELEMENTS FOR CONSIDERATION.—In defining the essential health benefits under paragraph (1), the Secretary shall—
(A) ensure that such essential health benefits reflect an appropriate balance among the categories described in such subsection, so that benefits are not unduly weighted toward any category;
(B) 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;
(C) take into account the health care needs of diverse segments of the population, including women, children, persons with disabilities, and other groups;
(D) 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;
(E) provide that a qualified health plan shall not be treated as providing coverage for the essential health benefits described in paragraph (1) unless the plan provides that—
(i) coverage for emergency department services will be provided without imposing any requirement under the plan for prior authorization of services or any limitation on coverage where the provider of services does not have a contractual relationship with the plan for the providing of services that is more restrictive than the requirements or limitations that apply to emergency department services received from providers who do have such a contractual relationship with the plan; and
(ii) if such services are provided out-of-network, the cost-sharing requirement (expressed as a copayment amount or coinsurance rate) is the same requirement that would apply if such services were provided in-network;
(F) provide that if a plan described in section 1311(b)(2)(B)(ii) (relating to stand-alone dental benefits plans) is offered through an Exchange, another health plan offered through such Exchange shall not fail to be treated as a qualified health plan solely because the plan does not offer coverage of benefits offered through the stand-alone plan that are otherwise required under paragraph (1)(J); and
(G) periodically review the essential health benefits under paragraph (1), and provide a report to Congress and the public that contains—
(i) an assessment of whether enrollees are facing any difficulty accessing needed services for reasons of coverage or cost;
(ii) an assessment of whether the essential health benefits needs to be modified or updated to account for changes in medical evidence or scientific advancement;
(iii) information on how the essential health benefits will be modified to address any such gaps in access or changes in the evidence base;
(iv) an assessment of the potential of additional or expanded benefits to increase costs and the interactions between the addition or expansion of benefits and reductions in existing benefits to meet actuarial limitations described in paragraph (2); and
(H) periodically update the essential health benefits under paragraph (1) to address any gaps in access to coverage or changes in the evidence base the Secretary identifies in the review conducted under subparagraph (G).
(5) RULE OF CONSTRUCTION.—Nothing in this title shall be construed to prohibit a health plan from providing benefits in excess of the essential health benefits described in this subsection.
(c) REQUIREMENTS RELATING TO COST-SHARING.—
(1) ANNUAL LIMITATION ON COST-SHARING.—

(A) 2014.—The cost-sharing incurred under a health plan with respect to self-only coverage or coverage other than self-only coverage for a plan year beginning in 2014 shall not exceed the dollar amounts in effect under section 223(c)(2)(A)(ii) of the Internal Revenue Code of 1986 for self-only and family coverage, respectively, for taxable years beginning in 2014.
(B) 2015 AND LATER.—In the case of any plan year beginning in a calendar year after 2014, the limitation under this paragraph shall—
(i) in the case of self-only coverage, be equal to the dollar amount under subparagraph (A) for self only coverage for plan years beginning in 2014, increased by an amount equal to the product of that amount and the premium adjustment percentage under paragraph (4) for the calendar year; and
(ii) in the case of other coverage, twice the amount in effect under clause (i).
If the amount of any increase under clause (i) is not a multiple of $50, such increase shall be rounded to the next lowest multiple of $50.
(2) ANNUAL LIMITATION ON DEDUCTIBLES FOR EMPLOYER-SPONSORED PLANS.—
(A) IN GENERAL.—In the case of a health plan offered in the small group market, the deductible under the plan shall not exceed—
(i) $2,000 in the case of a plan covering a single individual; and
(ii) $4,000 in the case of any other plan.
The amounts under clauses (i) and (ii) may be increased by the maximum amount of reimbursement which is reasonably available to a participant under a flexible spending arrangement described in section 106(c)(2) of the Internal Revenue Code of 1986 (determined without regard to any salary reduction arrangement).
(B) INDEXING OF LIMITS.—In the case of any plan year beginning in a calendar year after 2014—
(i) the dollar amount under subparagraph (A)(i) shall be increased by an amount equal to the product of that amount and the premium adjustment percentage under paragraph (4) for the calendar year; and
(ii) the dollar amount under subparagraph (A)(ii) shall be increased to an amount equal to twice the amount in effect under subparagraph (A)(i) for plan years beginning in the calendar year, determined after application of clause (i).
If the amount of any increase under clause (i) is not a multiple of $50, such increase shall be rounded to the next lowest multiple of $50.
(C) ACTUARIAL VALUE.—The limitation under this paragraph shall be applied in such a manner so as to not affect the actuarial value of any health plan, including a plan in the bronze level.
(D) COORDINATION WITH PREVENTIVE LIMITS.—Nothing in this paragraph shall be construed to allow a plan to have a deductible under the plan apply to benefits described in section 2713 of the Public Health Service Act.
(3) COST-SHARING.—In this title—
(A) IN GENERAL.—The term "cost-sharing" includes—
(i) deductibles, coinsurance, copayments, or similar charges; and
(ii) any other expenditure required of an insured individual which is a qualified medical expense (within the meaning of section 223(d)(2) of the Internal Revenue Code of 1986) with respect to essential health benefits covered under the plan.
(B) EXCEPTIONS.—Such term does not include premiums, balance billing amounts for non-network providers, or spending for non-covered services.
(4) PREMIUM ADJUSTMENT PERCENTAGE.—For purposes of paragraphs (1)(B)(i) and (2)(B)(i), the premium adjustment percentage for any calendar year is the percentage (if any) by which the average per capita premium for health insurance coverage in the United States for the preceding calendar year (as estimated by the Secretary no later than October 1 of such preceding calendar year) exceeds such average per capita premium for 2013 (as determined by the Secretary).
(d) LEVELS OF COVERAGE.—
(1) LEVELS OF COVERAGE DEFINED.—The levels of coverage described in this subsection are as follows:
(A) BRONZE LEVEL.—A plan in the bronze level shall provide a level of coverage that is designed to provide benefits that are actuarially equivalent to 60 percent of the full actuarial value of the benefits provided under the plan.
(B) SILVER LEVEL.—A plan in the silver level shall provide a level of coverage that is designed to provide benefits that are actuarially equivalent to 70 percent of the full actuarial value of the benefits provided under the plan.

(C) GOLD LEVEL.—A plan in the gold level shall provide a level of coverage that is designed to provide benefits that are actuarially equivalent to 80 percent of the full actuarial value of the benefits provided under the plan.
(D) PLATINUM LEVEL.—A plan in the platinum level shall provide a level of coverage that is designed to provide benefits that are actuarially equivalent to 90 percent of the full actuarial value of the benefits provided under the plan.
(2) ACTUARIAL VALUE.—
(A) IN GENERAL.—Under regulations issued by the Secretary, the level of coverage of a plan shall be determined on the basis that the essential health benefits described in subsection (b) shall be provided to a standard population (and without regard to the population the plan may actually provide benefits to).
(B) EMPLOYER CONTRIBUTIONS.—[As revised by section 10104(b)(1)] The Secretary shall issue regulations under which employer contributions to a health savings account (within the meaning of section 223 of the Internal Revenue Code of 1986) may be taken into account in determining the level of coverage for a plan of the employer.
(C) APPLICATION.—In determining under this title, the Public Health Service Act, or the Internal Revenue Code of 1986 the percentage of the total allowed costs of benefits provided under a group health plan or health insurance coverage that are provided by such plan or coverage, the rules contained in the regulations under this paragraph shall apply.
(3) ALLOWABLE VARIANCE.—The Secretary shall develop guidelines to provide for a de minimis variation in the actuarial valuations used in determining the level of coverage of a plan to account for differences in actuarial estimates.
(4) PLAN REFERENCE.—In this title, any reference to a bronze, silver, gold, or platinum plan shall be treated as a reference to a qualified health plan providing a bronze, silver, gold, or platinum level of coverage, as the case may be.
(e) CATASTROPHIC PLAN.—
(1) IN GENERAL.—A health plan not providing a bronze, silver, gold, or platinum level of coverage shall be treated as meeting the requirements of subsection (d) with respect to any plan year if—
(A) the only individuals who are eligible to enroll in the plan are individuals described in paragraph (2); and
(B) the plan provides—
(i) except as provided in clause (ii), the essential health benefits determined under subsection (b), except that the plan provides no benefits for any plan year until the individual has incurred cost-sharing expenses in an amount equal to the annual limitation in effect under subsection (c)(1) for the plan year (except as provided for in section 2713); and
(ii) coverage for at least three primary care visits.
(2) INDIVIDUALS ELIGIBLE FOR ENROLLMENT.—An individual is described in this paragraph for any plan year if the individual—
(A) has not attained the age of 30 before the beginning of the plan year; or
(B) has a certification in effect for any plan year under this title that the individual is exempt from the requirement under section 5000A of the Internal Revenue Code of 1986 by reason of—
(i) section 5000A(e)(1) of such Code (relating to individuals without affordable coverage); or
(ii) section 5000A(e)(5) of such Code (relating to individuals with hardships).
(3) RESTRICTION TO INDIVIDUAL MARKET.—If a health insurance issuer offers a health plan described in this subsection, the issuer may only offer the plan in the individual market.
(f) CHILD-ONLY PLANS.—If a qualified health plan is offered through the Exchange in any level of coverage specified under subsection (d), the issuer shall also offer that plan through the Exchange in that level as a plan in which the only enrollees are individuals who, as of the beginning of a plan year, have not attained the age of 21, and such plan shall be treated as a qualified health plan.
(g) PAYMENTS TO FEDERALLY-QUALIFIED HEALTH CENTERS.—
[As added by section 10104(b)(2).] If any item or service covered by a qualified health plan is provided by a Federally-qualified health center (as defined in section 1905(1)(2)(B) of the Social Security Act (42 U.S.C. 1396d(1)(2)(B)) to an enrollee of the plan, the offeror of the plan shall pay to the center for the item or service an amount that is not less than the amount of payment that would have been paid to the center under section 1902(bb) of such Act (42 U.S.C. 1396a(bb)) for such item or service.

Appendix B

Web-Based Questions for Public Input on Determination of Essential Health Benefits

The committee provided opportunity for public input via online submission of responses to the following set of questions. All responses were placed in the project's public access file, provided directly to HHS, and analyzed for the IOM committee's review in developing its separate publication, *Essential Health Benefits: Balancing Coverage and Cost*.

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

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

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?

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?

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?

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.

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?

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?

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 all current state mandates in requirements for a national essential benefit package?

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?

Appendix C

Stanford Model Contractual Language for Medical Necessity

In the late 1990s, a research team convened by Stanford University developed model contract language for medical necessity, as follows:

For contractual purposes, an intervention will be covered if it is an otherwise covered category of service, not specifically excluded, and *medically necessary.* An intervention may be medically indicated yet not be a covered benefit or meet this contractual definition of *medical necessity.* A health plan may choose to cover interventions that do not meet this contractual definition of *medical necessity.*

An intervention is *medically necessary* if, as recommended by the treating physician[1] and determined by the health plan's medical director or physician designee,[2] it is all of the following:

A health intervention[3] for the purpose of treating a medical condition; the most appropriate supply or level of service, considering potential benefits and harms to the patient; known to be effective[4] in improving health outcomes.[5] For new interventions,[6] effectiveness is determined by scientific evidence.[7,8] For existing interventions,

[1] Treating physician means a physician who has personally evaluated the patient.

[2] Physician designee means a physician designated to assist in the decision-making process.

[3] A health intervention is an item or service delivered or undertaken primarily to treat (i.e., prevent, diagnose, detect, treat, or palliate) a medical condition (i.e., disease; illness; injury; genetic or congenital defect; pregnancy; or a biological or psychological condition that lies outside the range of normal, age-appropriate human variation) or to maintain or restore functional ability. For the contractual definition of medical necessity, a health intervention is defined not only by the intervention itself, but also by the medical condition and patient indications for which it is being applied.

[4] Effective means that the intervention can reasonably be expected to produce the intended results and to have expected benefits that outweigh potential harmful effects.

[5] Health outcomes are outcomes that affect health status as measured by the length or quality (primarily as perceived by the patient) of a person's life.

[6] An intervention is considered to be new if it is not yet in widespread use for the medical condition and patient indications being considered.

[7] Scientific evidence consists primarily of controlled clinical trials that either directly or indirectly demonstrate the effect of the intervention on health outcomes. If controlled clinical trials are not available, observational studies that demonstrate a causal relationship between the intervention and health outcomes can be used. Partially controlled observational studies and uncontrolled clinical series may be suggestive, but do not by themselves demonstrate a causal relationship unless the magnitude of the effect observed exceeds anything that could be explained either by the natural history of the medical condition or potential experimental biases.

[8] New interventions for which clinical trials have not been conducted because of epidemiological reasons (i.e., rare or new diseases or orphan populations) shall be evaluated on the basis of professional standards of care or expert opinion (as described in footnote 9).

effectiveness is determined first by scientific evidence, then by professional standards, then by expert opinion;[9] and cost-effective for this condition compared to alternative interventions, including no intervention.[10] "Cost-effective" does not necessarily mean lowest price.

REFERENCE

Singer, S., L. Bergthold, C. Vorhaus, S. Olson, I. Mutchnick, Y. Y. Goh, S. Zimmerman, and A. Enthoven. 1999. *Decreasing variation in medical necessity decision making. Appendix B.* Model language developed at the "Decreasing Variation in Medical Necessity Decision Making" Decision Maker Workshop in Sacramento, CA, March 11-13, 1999.

[9] For existing interventions, the scientific evidence should be considered first and, to the greatest extent possible, should be the basis for determinations of medical necessity. If no scientific evidence is available, professional standards of care should be considered. If professional standards of care do not exist, or are outdated or contradictory, decisions about existing interventions should be based on expert opinion. Giving priority to scientific evidence does not mean that coverage of existing interventions should be denied in the absence of conclusive scientific evidence. Existing interventions can meet the contractual definition of medical necessity in the absence of scientific evidence if there is a strong conviction of effectiveness and benefit expressed through up-to-date and consistent professional standards of care or, in the absence of such standards, convincing expert opinion.

[10] An intervention is considered cost effective if the benefits and harms relative to costs represent an economically efficient use of resources for patients with this condition. In the application of this criterion to an individual case, the characteristics of the individual patient shall be determinative.