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M E M O R A N D U M

To: **American Society of Transplant Surgeons**

From: Peter W. Thomas; Theresa T. Morgan

Date: January 28, 2011

Re: **IOM January Committee Meeting On Essential Health Benefits**

Background

The Patient Protection and Affordable Care Act (ACA) mandates that in 2014 all individual and small group insurance plans operating through new state insurance exchanges cover a list of benefit categories known as the "essential health benefits" (EHB) package. The Department of Health and Human Services (HHS) is expected to issue its initial proposed rule on the EHB this fall. In advance of this proposed rulemaking, HHS will receive data from the Institute of Medicine (IOM) and the Department of Labor (DOL) related to the criteria and scope of the EHB as well as data on the scope of coverage provided by typical employer plans.

The ACA requires the DOL to conduct a survey of employers to determine the scope of benefits within the "typical employer plan" (TEP) and to limit the essential benefits package to a plan equal to the TEP. In December, William Wiatrowski, Associate Commissioner for Compensation and Working Conditions at the Bureau of Labor Statistics (BLS), hosted with colleagues at DOL and HHS a briefing describing the protocol for their survey and the limitations they are facing in determining the TEP. Because of time and resource constraints, the DOL is using 2008 and 2009 National Compensation Survey (NCS) data instead of conducting a new survey.

Unfortunately, there is every indication that DOL will have little coverage data on critical benefits such as rehabilitation and habilitation services, prosthetics, orthotics, durable medical equipment, end stage renal disease care, organ transplantation, behavioral health services, and a series of other benefits that are listed in the ACA but data for such benefits are not routinely collected by DOL. Because of this, *it is important for organizations representing these constituencies to provide as much data as possible to the DOL and IOM on coverage of these benefits under typical employer plans* (see, recommendation at end of this memorandum).

HHS has also contracted with the IOM, asking the Institute to conduct a consensus study and provide HHS with recommendations on the criteria to be used for determining the EHB. In advance of last week's meeting, the IOM published an online survey to which over 300 stakeholders responded. In response to those submissions, the study chairs contacted rehabilitation stakeholders and requested they present at the first public meeting of the IOM's Committee on the Determination of Essential Health Benefits. On January 13, Peter Thomas, co-chair of the Consortium for Citizens with Disabilities (CCD's) Heath Task Force and Marty Ford, co-chair of CCD's Long Term Service and Supports Task Force, focused on rehabilitation and habilitation, respectively.

The IOM also heard from a number of prominent panelists for a few minutes each on January 14. The American Medical Association, American Hospital Association, and the National Kidney Foundation all testified. Troy Zimmerman, Vice President for Government Relations at NKF, made a number of critical points. He stressed that plans should not limit the modality or number of dialysis sessions for a patient if the patient and his or her health team agree more frequent dialysis is beneficial; and that access to kidney transplantation, whether from a living donor or deceased donor, and access to repeated transplants after graft failure also should not be limited. Zimmerman's testimony can be found here.

IOM Meeting On Essential Health Benefits

On January 12-14, the Institute of Medicine's Committee on the Determination of Essential Health Benefits held its first public meeting to explore its charge, given by HHS, of recommending criteria and methods for establishing and updating the essential health benefit package, as created by the ACA. For the meeting agenda, please click here; for a listing of links to testimony, here; and for a description of the committee's work, please visit their home site.

A majority of the panelists presented their analysis of Section 1302 of the ACA, the essential benefit package section of the law, along with their experience in the health insurance world, from the perspective of affordability and scope of the benefits package. Other related issues that were discussed included medical necessity, balance between categories of benefits, state mandates and nondiscrimination.

This memorandum highlights and details the testimony provided at the first day of the public meeting, what IOM called a "workshop," and is organized by topic areas discussed in depth at the meeting.

I. HHS Guidance for the IOM Study on Essential Health Benefits

Sherry Glied, Assistant Secretary for Planning and Evaluation of HHS, presented first to the Committee. As the funder of the IOM study, he requested on behalf of HHS, that the Committee answer a series of questions, including:

- At what level of specificity should the package be defined?
- What should be the scope of coverage?

- What are your thoughts on medical vs., non-medical services? How should that be defined?
- How should the federal standard address state mandates?
- How much flexibility should we give states with exchanges?
- How can we learn from employers that offer multiple employer plans?
- What information is needed to monitor the decisions and actions of plans?
- What should be the role of state and federal governments?
- What should be the EHB updating process?

Glied also referenced the tension between defining the essential benefits package based on the typical employer plan (TEP) with the need to include criteria to ensure an appropriate balance of benefits and prevent discrimination against consumers based on disability, age and other factors listed in the statute. She acknowledged that, while ACA requires that the TEP be used as a "benchmark" on the scope of the essential health benefits, prior to implementation of the statute, the typical employer plan has not been required to meet the non-discrimination clauses of the ACA. Glied requested the committee to address how to balance these requirements in establishing the EHB package.

In response to questions about the potential cost of the package, Glied responded that she does not think the role of this committee is to "cost out" a benefits package, but that the committee should be mindful of affordability when recommending its criteria. (This statement stands in stark contrast to advice given to the committee from multiple speakers later in the day who even suggested that the IOM hire a health economist to assist the committee in calculating the expenses of adding any benefit to the essential benefits package.)

II. Congressional Intent for Scope of Benefits Package

Former Congressional staffers who participated in the drafting of the ACA then testified on selection of the categories of the essential health benefits that are outlined in the bill. **Mark Hayes, former Republican Health Policy Director and Chief Health Counsel for the Senate Finance Committee**, commented on the portion of the EHB section that was formulated by the Committee. He stated that although the non-discrimination criteria was added later in the process and, therefore, he would not speak to those provisions, he could attest that the basic benefit categories were developed with the Federal Employee Health Benefits Program (FEHBP) and the Massachusetts health package as models. Hayes said that the Medicare, Medicare Advantage, and Supplemental plans were all considered and rejected as models. Hayes said that the lengthy and detailed health benefits plan within the Health Security Act in 1993 and '94 was also rejected in favor of the broad categories within the Massachusetts plan and the FEHBP.

Hayes stated that the essential health benefits package was meant to mark a minimum standard of benefits to be met by qualified health plans (QHPs). He also remarked that the broad categories were intentional and that Congress did not intend for the HHS Secretary to define a detailed package at the federal level. Hayes said that the detailed benefit designs should be defined in the private market, with the broad categories and actuarial values as parameters. He also added a caution that the lowest level of benefits, the "Bronze" package, would end up having high cost sharing if the benefits package was defined at the federal levels and high costs

for the lowest level plan would be self-defeating.

Katy Spangler, Republican Senior Health Policy Advisor for the Senate HELP Committee, testified that although the essential benefits package was modeled after the FEHBP, the FEHBP is actually narrower than the EHB package. She stated that there was in Congress "extreme concern" during the health reform debate about increasing premiums and that Congress intended the TEP to be limited by the typical *small* employer plan, not the typical large employer plan. Spangler argued that the more HHS mandates benefits within the EHB package, the higher the costs will be, and that this will result in less people purchasing insurance than if insurance were more affordable. Spangler emphasized that she believes it is "critical" that HHS not "overreach" in defining essential health benefits, and that the IOM should look at the "least robust standard" when defining the EHB package.

David Schwartz, Health Counsel, Senate Finance Committee Democratic Staff, on the other hand, testified that Congress intended the broad categories to lead to a "robust" benefit package. Congress did not intend to limit coverage to just outpatient services, he asserted. Rather, Congress intended that the benefit package must be defined so that it is meaningful for consumers. Schwartz continued that plans are free to offer more benefits above the EHB, similar to the design of the FEHB, and that plans will likely offer additional benefits over the minimum EHB. Schwartz also argued that the design should be flexible enough to allow for innovation and to allow for change over time. He argued for broad, flexible and affordable coverage.

David Bowen, former Democratic Director of Health Policy of the Senate HELP Committee, argued forcefully that Congress intended a robust benefits package. Bowen stated that it was a deliberate decision to offer categories rather than detailed benefits within the law and that the categories are intended to be typical of a *large* employer plan. This was in contrast to Spangler's testimony. Bowen argued that the general understanding on the Hill at the time of drafting was that the EHB reflects a relatively generous package.

Bowen did allude to what limitations would be consistent with Congressional intent. He stated that the ACA explicitly does not list the number of services that can be offered under the package, and that HHS will need to sort out a "volume and scope" of benefits under each category.

In response to questions about whether Congress intended the scope of the benefits package to include state mandates, Hayes replied that at the time of drafting, staff did not want to take on the issue of which benefits mandated at the state level should or should not survive on the federal level. Hayes remarked that they recognized it would be extremely controversial and chose against making those decisions. He brought attention to the fact that the statute calls for the development of a federal standard, and that if states required benefits beyond that standard, they would have to pay the difference by adding state subsidies to the statute's federal subsidies. Schwartz remarked that some state mandated benefits made sense in particular states but not for other states. He argued that the federal law needs enough flexibility so that it is not infringing on the ability of states to offer additional benefits.

It did appear that the Committee was receiving consistent messages from panelists on flexibility and the idea that the package was intended as a floor above which plans could offer additional benefits, but very inconsistent messages on whether that floor should be defined as a robust benefits package or a narrow one. This, of course, if the key issue that HHS will have to determine.

III. Department of Labor: Defining the Typical Employer Plan (TEP)

The ACA requires the DOL to conduct a survey of employers to determine the scope of benefits within the TEP. The law directs HHS to certify that the scope of the EHB package is equal to the TEP. **William Wiatrowski, Associate Commissioner for Compensation and Working Conditions at the Bureau of Labor Statistics (BLS)** described the protocol for their research and the limitations they are facing in determining the TEP. Because of time and resource constraints, the DOL is using 2008 and 2009 National Compensation Survey (NCS) data instead of conducting a new survey. For the NCS, the BLS samples different sizes of private and state employers. For purposes of making an assessment of the TEP, the BLS is sampling plans from 3200 employers, both self-insured and fully funded.

Since the employers' submission to BLS is voluntary and since there is no standard reporting requirement or protocol, the data received by the BLS is variable and inconsistent in its detail. BLS is surveying this data for a list of services that would presumably be included in the typical employer plan. Wiatrowski admitted there are limitations in this survey protocol, namely that statute requires the gathering of data for certain benefits that the current survey does not include, such as data about rehabilitative and habilitative services and other important benefits. Wiatrowski suggested the DOL was open to changing the protocol, which will be imperative for services that are not covered by the current protocol – particularly if DOL continues to be involved in updating the EHB package in future years.

IV. Understanding "Minimum Benefits"

Throughout the day, testimony of different panelists represented the tension between providing a robust essential benefits package and an affordable package. In addition, when panelists discussed affordability, their opinions varied widely on whether to control costs by limiting benefits or by using the package design, or both.

Jonathan Gruber, Professor of Economics at MIT and Director of the Health Care Program at the National Bureau of Economics Research, spoke about his experience as a member of the Massachusetts Connector Board that set the state's "Minimum Creditable Coverage" standard. He described the dilemma of trying to offer generous benefits at an affordable price. Gruber also spoke to the need for minimizing disruption, arguing that offering more generous coverage from what most people now have will increase prices in the market and create destabilization.

Gruber stated that ACA "rightly" removes annual and lifetime limits as limitations on essential heath benefits. But, he said, the law does not rule out more specific limits on benefits and gave the examples of limiting the number of days for outpatient mental health coverage or the number

of physical therapy visits. Gruber also said that the bill does not prohibit STEP therapy where coverage for one service is only permitted if another, less costly or intensive service, is tried and is not effective.

Gruber also pointed out that the ACA specifies and out-of-pocket maximum as a function of income, but falls short of specifying to what the out-of-pocket maximum applies. He recommended the IOM provide guidance to ensure that the restriction affects a broad range of benefits.

Gruber continually emphasized the need for the IOM to consult a number of disinterested actuaries. He said that especially if the Committee were to plan on adding to the EHB package, it would need to be informed of the associated costs. Gruber stated that based on his data, a 10 % increase in the cost of benefits added to the EHB package articulated in the statute would increase costs to the federal government by 14% (70 billion over 10 years) and would lead to 1.5 million people no longer being required to purchase insurance because financial hardship clause in the statute.

Gruber also argued in favor of creating looser standards and a less flexible appeals process in order to limit appeals. He said that tighter rules leads to more appeals. In general, he argued the Committee should start modest, be wary of additional mandates that would add to cost and undercut support for the broader framework of the law, and set up a dynamic and flexible design.

V. Criteria and Methods for Defining and Updating Individual Mandates and Packages

Purchaser Perspectives

Jerry Malooley, Director of Health Policy and Benefit Program Design for the State of Indiana, spoke on behalf of the Chamber of Commerce. Malooley recommended against including state mandates within the EHB package. She strongly urged the committee to set criteria for a modest, "bare-bones" package. **Helen Darling, from the Washington Business Group on Health,** testified that most of their large employers give employees choice between different levels of packages. Darling said that along with choice, evidence should be created and developed to use as a "feedback loop" to inform the minimum, or floor, benefits package. Darling also argued that individuals need to be protected from catastrophic losses and that demonstrated evidence should inform comparative effectiveness design to protect consumers from wasteful and harmful care. Health care plans should be consumer-directed, argued Darling, and that the information provided to consumers needs to include "decision aids."

Darling used an example of an employee that had MS and needed access to care that initially was not determined to be covered by the plan. A review of the evidence showed that the care would lessen deterioration of function for the individual, and so the plan was modified to incorporate that treatment based on clinical evidence. Though plans will not cover rehabilitation at 100 percent, Darling continued, IOM will need to determine the balance. Darling argued that payers could use plan design to bring down costs.

State Perspectives

Jon Kingsdale, Managing Director of the Wakely Consulting Group, discussed the Massachusetts experience in defining a minimum benefits package. Kingsdale argued for the need to make decisions based on a set of principles, and recommended the following three:

1) This effort is mostly about providing decent coverage;
2) Affordability is key;
3) Many states that have benefit requirements do not mandate specific benefit language.have specific benefit language.

Kingsdale argued for a smaller benefits package, and against letting states decide on a state-by-state basis what is in the EHB. Kingsdale also stated there is also the potential to phase the process in and that the IOM could recommend a process for coverage exceptions.

Beth Sammis, Acting Insurance Commissioner for the Maryland Insurance Administration, testified that in Maryland, medical necessity if left up to the carrier to define. All carriers submit their medical necessity criteria to the administration and it is evaluated. The law provides some broad standards, and if a plan's medical necessity determination is appealed, the administration reviews it to ensure the plan is following the standards set out in law. The Commissioner has the authority to overturn a plan's decision and to ensure that the plan adjusts their medical necessity criteria if necessary. In addition, the administration has the ability to ensure their competitors' criteria is in line with the changes.

Rex Cowdry, the Director of the Maryland Health Care Commission, discussed the tension between the breadth of coverage and the cost of benefits. Cowdry argued that the federal package should remain broad and that states should be allowed to experiment with different limits and tighten up the definition of EHB package if costs increase.

James Dunnigan, Utah State House of Representatives and insurance broker, argued that the notion of "typical" in the TEP should be decided on a state-by-state basis and at the state level, allowing for the recognition of state mandates. He offered recommendations for three tiers of benefits:

Tier 1: TEP defined within that state;
Tier 2: HHS Secretary's federal definition of the TEP that exceeds state benefits;
Tier 3: Anything beyond the Secretary's plan, the states would fund.

Matt Salo from the National Governor's Association stated that the NGA has been convening to discuss key issues around the exchange, even before passage of ACA. He said that the consensus is reflective of the opinions of the other state panelists: that even with the passage of the ACA, health insurance is largely a local or state issue. He also argued that the political and regulatory differences that drive state decisions are legitimate. Salo agreed with Dunnigan that decisions should be made on a state-by-state basis and he said governors will need a highly flexible framework for what the benefits should look like. He argued that federal "granular"

direction on the amount, duration and scope of benefits would not be helpful. Salo said that altering the design of the package toward value-based benefit design would be helpful.

Gruber spoke up at the end of this discussion to argue that the IOM is not tasked with "punting" to the states, but with developing a national package. Committee members noted that they would be looking to experiences in Maryland, Utah, and Massachusetts for their criteria around cost sharing, the benefits package, and the package design, and reviewing the impact of these policies.

VI. Medical Appropriateness and Medical Necessity

Alan Garber, Director of the Center for Health Policy and Director for Primary Care and Outcomes Research at Stanford University, testified that coverage and medical necessity are separate, though related, ideas. Garber said that coverage decisions are policy decisions about categories of health interventions provided to a population as part of a statutory mandate; a medical necessity decision is about the appropriateness of a specific treatment for a specific patient. Some things that are medically necessary are uncovered; some covered benefits are not medically necessary.

Garber talked about the Second Circuit Court of Appeals decision that stated unless the contrary is specified, the term "medical necessity" must refer to what is medically necessary for a particular patient and not a general determination of what works in a general case. The Stanford definition of medical necessity, which has been adopted by some state Medicaid and private plans, is based on five criteria:

1) Decision making authority
    a. Treating physician and Medicaid plan's medical director
2) Purpose of the intervention
    a. Intervention to treat medical condition
3) Scope of the intervention
    a. Appropriate level of service considering benefits and harms to patient
4) Standards of evidence
    a. Known to be effective in improving health outcomes
5) Value (cost effectiveness)
    a. Controlled clinical trials or observational studies demonstrating the effect of the intervention on health outcomes
    b. New interventions evaluated on the basis of professional standards of care or expert opinion
    c. For existing interventions, evidence used first or professional standards if evidence does not exist, or convincing expert opinion if professional standards do not exist.

Garber identified several key issues of medical necessity moving forward:

1. Fair processes and public involvement

2. More expansive definitions will increase cost
3. Accommodating individual variation in the ability to benefit from specific treatments.

Barbara Warren, from Consumers United for Evidence-based Healthcare, testified that it is critical to develop a consistent, universal definition of medical necessity that emphasizes quality and clinical effectiveness above cost and resource utilization. She also promoted the principle of full consumer inclusion in the development and implementation of policies and guidelines that determine access to care.

VII. Insurers Policies Regarding Benefit Design, Medical Necessity and Coverage

Jeffrey Kang, Chief Medical Officer of Cigna, testified that the purpose of medical necessity is to ensure that the service that was provided is reasonable, necessary and effective. He stated that there are some services that go uncovered regardless of medical need, such as investigational services. Kang pointed out that some of the categories of services listed in the EHB are traditionally uncovered in an essential health benefits, or uncovered unless an employer buys a more expensive plan. He said that wellness and pediatric services for oral and vision care are usually available as a "buy-up" option, but that habilitation is usually uncovered even in more expensive plans. Kang also referred to a grid Cigna developed illustrating their recommendation for tiered plans. Cigna recommends that plans should control costs by varying the benefits offered. The minimum bronze plan would include "life-preserving" services, while only the more expensive plans would include chronic disease management and "life-enhancing" services, such as rehabilitation.

Robert McDonough, Director of Clinical Policy Research and Development for Aetna, recommended that the Committee preserve medical management tools, like medical necessity. He also made the point that medical necessity should be considered after the benefit package is designed, and should not be a factor in the designation of the essential benefits package.

Carmella Bocchino from America's Health Insurance Plans (AHIP) also testified that medical necessity review only is used when medical evidence is in question. The vast majority of claims are routinely paid without specific review of medical necessity. She also emphasized the importance of keeping the benefit package modest to reduce costs.

VIII. Specific Categories of Care

<u>Mental Health and Substance Use Disorder Services, Including Behavioral Health Treatment</u>

Kenneth Wells, Senior RAND Scientist and Professor of Psychiatry and Behavioral Sciences at UCLA, and his colleague at UCLA, Kavita Patel, testified that most people with severe mental illness are covered by the publicly supported programs and are not in private plans, largely because the private sector does not have the infrastructure to serve that population as a result of years of not being required to serve that population. Wells also argued that "essential" needs to include the full spectrum of mental health benefits. Wells stated that the IOM and HHS cannot use the "typical" plan as a benchmark and that essential should not be

ratcheted down to the minimum. Parity prohibits quantitative limitations, they argued, and medical management can be no more restrictive for mental health than for medical surgical interventions under the language of the statute.

Rehabilitative and Habilitative Services and Devices

Peter Thomas, Co-chair of the Consortium for Citizens with Disabilities Health Task Force and Principal at Powers, Pyles, Sutter and Verville, testified that Congress intended for the category "rehabilitative and habilitative services" to include rehabilitation services that improve, restore and prevent the deterioration of function, in a variety of settings of intensity to meet the individual needs of the patient. He also stated that "rehabilitation devices" were intended to include coverage of durable medical equipment, orthotics, prosthetics, and supplies. Thomas also testified that the ACA prohibits unreasonable restrictions and exclusions in one benefit category (e.g., rehabilitation) if similar restrictions are not placed on other categories. Thomas recommended that the HHS and IOM consider the limitations of the DOL study when determining the impact of the TEP on the determination of the EHB package. Thomas pointed out that the ACA states that essential benefits must not be subject to denial to individuals against their wishes on the basis of the individual's present or predicted disability, degree of medical dependency or quality of life. Thomas said that the disability community is concerned that the EHB could wind up becoming a ceiling rather than a floor of benefits, especially if employer plans begin to pare down their coverage to match a narrowly defined EHB.

Marty Ford, with The Arc and United Cerebral Palsy Disability Policy Collaboration, and on behalf of the CCD Long Term Services and Supports Task Force, testified that providing habilitation services prevents costly institutionalization and enables people to function better in the community. Habilitation services are critical to the success of young children with disabilities who need to acquire essential skills to ensure successful development and learning and for adults to live independently in the community, Ford said. Ford added that the provision of habilitation services can also prevent frequent hospitalization or emergency room visits because people are maintaining their function.

Gary Ulicny, President and CEO of the Shepherd Center and President of the American Congress of Rehabilitation Medicine, testified that under current coverage practices, arbitrary limitations are not atypical regardless of diagnosis, that current reimbursement models do not incentivize optimal rehabilitation, and that a strict definition of medical necessity is often based on the assumption that plans will not have long-term exposure to patients. Ulicny recommended that any benefit limitations should be evidence-based, a formal advisory committee should be created to update the benefits package, and that HHS should examine alternative reimbursement strategies that reward performance.

Committee members asked challenging questions regarding the medical device industry and the evidence-base for their use and for other treatment interventions.

IX. Additional Legislative Guidance

Sara Rosenbaum, Hirsh Professor and Chair of the Department of Health Policy and Health Services at George Washington University, testified that the Committee should focus on practices that will limit insurance coverage, since insurance plans traditionally "limit below the evidence" and do not fully justify their limitations based on the evidence.

Rosenbaum highlighted the fact that for the first time, the ACA extends disability nondiscrimination protections to health insurance, a major change in public policy. She cautioned against using condition-based exclusions or limitations of benefits because those could violate the nondiscrimination language of the statute.

In addition, Rosenbaum agued that the Committee should resist defining medically necessary as 1) limited by a condition and 2) limited by the notion of "recovery." She said the Committee should use guidelines supported by evidence and supported an idea from the committee to use as a condition of coverage a requirement that providers participate in an evidence-gathering program when questions as to the medical efficacy of a treatment exist. As a marker, Rosenbaum said that content limits that are reasonable and not solely based on disability, age and other inappropriate factors, would likely be appropriate.

X. Conclusion from the First IOM Meeting

The Committee heard a wealth of testimony on affordability, scope and benefit design issues from a variety of perspectives at their first public meeting. The testimony on the anti-discrimination provisions of the bill was limited in comparison, although those that did speak to this issue did so thoroughly and persuasively. In sum, it is imperative that stakeholders weighing in on this process emphasize:

- Affordability (via limits on benefits or through benefit design);
- The contents of the typical employer plan in relation to rehabilitation, and
- The importance of developing criteria to assure the essential health benefits package does not discriminate against people based on disability or age.

The Committee will hold a second public meeting later this year. In March, the Committee is on schedule to receive limited data from the Department of Labor on the typical employer plan.

XI. Recommended Action Related to Essential Health Benefits

DOL has admitted that its data on the typical employer plan will be deficient in a number of benefit categories that are listed explicitly in the ACA statute. These benefits include rehabilitation and habilitation services and devices, mental health and substance use disorder services, behavioral health care services, chronic care coordination, end stage renal disease care, organ transplantation, and pediatric services.

Stakeholders engaged in these benefit category areas should seriously consider identifying additional data and submitting it to DOL, IOM and HHS at the earliest opportunity. Such data should focus on two main areas:

1. What the typical employer plan covers with respect to one or more of the categories listed above, and;

2. Evidence of the efficacy of these services and the cost-effectiveness of providing such benefits on short-term and long-term costs to the health system.