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Office of Health Plan Standards and Compliance Assistance
Employee Benefits Security Administration
Room N-5653
U.S. Department of Labor
200 Constitution Avenue, NW
Washington, D.C. 20210

Attention: MHPAEA Comments

RE: Request for Information Regarding the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008

Dear Sir or Madam:

This will provide our comments to the Request for Information (the "RFI") Regarding the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (the "MHPAEA") published in the *Federal Register* on April 28, 2009 (74 Fed. Reg. 19155).

UnitedHealth Group uses its resources and expertise to support consumers, patients, care providers, employers, and benefit sponsors, so that they can make more informed health care decisions. Our breadth of services and leadership in both private and public programs enable us to adapt to a constantly evolving environment in order to make health care more accessible, affordable, and personalized. As one of America's leading health care companies, UnitedHealth Group serves more than 70 million Americans each year. Partnering with more than 650,000 physicians and other care providers, 5,200 hospitals, 80,000 dentists, and 65,000 pharmacies in all 50 states, we touch nearly every aspect of health care delivery and financing. This includes UnitedHealth Group's subsidiary, OptumHealth, which manages mental health and substance use disorder services along with employee assistance program services for over 43 million people, making it the largest managed behavioral health organization in the country.

Mental health and substance use disorder treatment coverage is an essential component of the American healthcare system. The MHPAEA was carefully constructed by Congress and supported by a wide array of health care stakeholders including UnitedHealth Group, the health insurance industry at large, mental health providers and consumer advocacy groups because of its thoughtful and balanced construction of the law to support such coverage in a fair and

equitable manner. The regulations and guidance to be issued under the MHPAEA must be equally reasoned and balanced to ensure consistency with the law's language and intended goals.

UnitedHealth Group respectfully requests that the Department of Labor ("DOL") consider the following comments and responses to the RFI when issuing regulations and guidance with respect to the provisions of the MHPAEA. For ease of reference we have included each of the RFI's questions or requests for comments in bold italicized type followed by our response in plain text. Note: in a number of our responses we cite different sources of information. The citations for each section can be found as endnotes to that specific section.

A. (i) What policies, procedures, or practices of group health plans and health insurance issues may be impacted by MHPAEA? What direct or indirect costs would result? What direct or indirect benefits would result? Which stakeholders will be impacted by such benefits and costs?

The MHPAEA will impact a variety of policies, practices, and procedures for those companies issuing health insurance. Many of these impacts will also be felt both directly and indirectly by plan sponsors and participants. In assessing these impacts, and the associated costs and benefits, it is vital to review what the MHPAEA does and does not address.

The MHPAEA does not contain a coverage mandate. The MHPAEA does not define any mandate for a plan to provide coverage of mental health or substance use disorders nor does it define coverage requirements for any particular mental health or substance use disorder conditions or treatments. The law reserves to plans and health insurance carriers the right to define which diagnoses they will cover as mental health and substance use disorder benefits (subject to other applicable federal and state laws). While the hope would be that all major diagnoses for both mental health and substance use disorders would be covered, this will be a determination made by the plan sponsor or health insurance issuer in response to a variety of market-driven considerations. The control of the scope of the benefits offered or provided by the plan or health insurance coverage has been a part of plan design process historically and it is not anticipated that MHPAEA will change this process and therefore there should be little cost impact arising from this element of plan design. The cost implications of the MHPAEA are truly driven by the changes required by the MHPAEA in parity of treatment limitations, financial requirements and out-of-network coverage. The flexibility for plans to choose the scope of their coverage for which mental health and substance use disorder conditions and treatments will be provided by a plan is an important benefit for stakeholders as it broadens plan design choices and can allow plans and health insurance issuers to provide a wider variety of affordable options to consumers.

The MHPAEA clearly allows for the terms and conditions of the plan to be determined by the plan sponsor and health insurance issuers provided that the defined boundaries of the MHPAEA with respect to treatment limitations and financial requirements are applied. Any interpretation which expands beyond the language of the MHPAEA in an attempt to alter plans' and health insurance issuers' ability to define the terms and conditions of the plan

would have a critical and negative effect on the affordability of mental health and substance use disorder benefits under this law.

The MHPAEA does require plans to significantly alter the administration of financial requirements. Financial requirements must now be no more restrictive for mental health and substance use disorder benefits than they are for medical and surgical benefits.

Due to some ambiguity in the language of the law, there needs to be clear guidance in the regulations with respect to the language in the MHPAEA that states "there are no separate cost sharing requirements that are applicable only with respect to mental health or substance use disorder benefits." We strongly believe that the language in the law is written to allow for plans and health insurance issuers to have the flexibility to apply either separate or shared (also referred to as "integrated" or "combined") financial requirements to mental health and substance use disorder benefits. In the event of a plan applying separate financial requirements to mental health and substance use disorder benefits those requirements must: (a) not be applied only to mental health and substance use disorders – meaning the plan must have a similar requirement on the medical and surgical benefits of the plan; and (b) the financial requirement must be no more restrictive on the mental health and substance use disorder benefits than the similar requirement applied to the medical and surgical benefits.

The contrary interpretation would suggest that a plan must have combined cost sharing requirements. This interpretation would have a direct impact on the administrative cost of plans and create a disadvantage for a significant number of plan participants by increasing the cost sharing requirements applicable to their mental health and substance use disorder benefits. This today would result in limiting access to care and the duration of care both of which could result in fewer positive outcomes for members seeking mental health and substance use disorder treatment. This is not an isolated or small issue – as many plans do not utilize this plan design currently. For example, UnitedHealth Group's subsidiary that specializes in the administration of mental health and substance use disorder benefits currently administers plans that offer separate cost sharing requirements for over 5 million plan participants.

The administrative cost impact of this point is driven in some part by the fact that mental health and substance use disorder benefit administration and management is a highly specialized field and many plans and purchasers have chosen to directly contract with a specialized managed behavioral healthcare organizations (MBHOs) to administer the mental health and substance use disorder benefits under the plan (this is commonly referred to as a "carve-out"). In cases where plans utilize a carve-out arrangement there would be at least two organizations involved in the single shared financial requirement approach – the plan administrator for medical and surgical benefits and the plan administrator, or carve-out vendor, for mental health and substance use disorder benefits. These organizations would, in order to administer shared cost sharing requirements, have to develop and program interfaces which would allow the communication and sharing of accurate, confidential data (such as claims information to be applied to a deductible) in order to ensure accurate management of the benefit and the shared cost sharing requirement.

This is an intensive administrative process and there are significant costs connected with establishing and maintaining these interfaces which can vary widely based on the complexity or similarity of the systems and exchanges as well as the timing of data exchanges (real-time, daily, weekly etc.). A shared deductible in this context would require that the plan and its administrators build the necessary system interfaces to share and coordinate data exchanges which could have a range of cost from $420,000 - $750,000 for each interface required. The number of interfaces required will depend on the plan and number of different medical and surgical plan administrators as well as the number of mental health and substance use disorder benefits vendors it has, but for a typical health insurance issuer who needs to interface with 40-50 other plan administrators on behalf of its plan customers, the cost could be as much as $17 million to $30 million per plan administrator.

In addition, there can be a direct financial impact on the individual plan participant due to this specific issue. The impact to the plan participant due to a plan design that has integrated financial requirements can be significant and negative. The general assumption is that a shared deductible is less costly for the member since both costs – the cost of mental health and substance use disorder care as well as the cost of medical and surgical care – are applied toward the same deductible and out-of-pocket expense maximum. Theoretically this is true for some participants but not for participants in plans with medical deductibles of ≥$ 1,000, which is an increasingly common plan design.

As of 2007, between 12.5 and 14.8 million people nationally were enrolled in high deductible plans or plans where deductibles were greater than or equal to $1,000. (Reuther 2007). According to the Kaiser Family Foundation and Health Research & Educational Trust survey published in 2008, 8-9% of employer groups were going to offer only high deductible health plans as a cost saving option for the employers as plan sponsors during the next renewal period. With this shift to higher deductible plans, more members are faced with high first dollar payment for mental health and substance use disorder health services. It is well established that access to, and duration of, medical and surgical as well as mental health and substance use disorder services are negatively impacted by deductible and out-of-pocket expenses set at this level[1]. The Commonwealth Fund Biennial Survey of 2005 demonstrated the incremental effect of increasing deductibles on those seeking treatment even when ill [2] (See also Figure in appendix). In mental health and substance use disorder treatment the impact of high first dollar cost is even greater than it is for medical and surgical treatments. Price elasticity studies have shown that demand for mental health and substance use disorder health care is more sensitive to price than medical and surgical care. McGuire, Taube and Horgan estimated that a 1% increase in cost of services decreases demand for services by 0.4 – 1% in contrast to medical and surgical care where the decrease in demand is only 0.13 -0.16%.[3-5]

It is important to note that, in mental health and substance use disorder coverage the pattern of service use (utilization) is much higher (mental health and substance use disorder treatment episodes average eight (8) visits while medical and surgical treatment episodes average three (3) visits per episode of care) and more frequent (mental health and substance use disorder treatment frequency averages one (1) to two (2) visits per week while medical

and surgical treatment frequency averages one (1) visit per month). Thus, given the frequency and higher utilization for mental health and substance use disorder benefits, accumulation of costs is far quicker for participants accessing these benefits. Many studies have demonstrated the sensitivity of access and duration of treatment in mental health and substance use disorder care, especially substance use disorder care, to financial requirements set by higher cost sharing models.[6-9] For example, for substance use disorders a $10 increase in cost sharing resulted in a 1% increase in the probability of a treatment reoccurrence due to a resultant shortening of the episode of prior care.[10 – 11]

With these factors in mind, it is important that plans have the ability to construct separate lower deductible and out-of-pocket expense maximums for plan participants faced with high medical and surgical expense deductibles and out-of-pocket expense maximums in order to allow members to have less of a financial disincentive and barrier to accessing mental health and substance use disorder health treatment which will ensure they receive necessary treatment when they need it. Guidance from research suggests levels of ideal copayment, deductible and out-of-pocket expense maximums that will have less impact on access and utilization of services.[1,7,12] Plans have historically been unwilling to adjust the medical deductible to accommodate mental health and substance use disorder health needs since it is estimated that approximately 95% of plan participants only access the medical and surgical benefits. Absent the ability to have separate cost sharing requirements for mental health and substance use disorder benefits which are no more restrictive than the similar requirements for medical and surgical benefits, purchasers are forced to utilize higher shared cost sharing requirements that are applied to both medical and surgical benefits as well as mental health and substance use disorder benefits with resulting significant negative cost and treatment effects for those participants who need mental health and substance use disorder treatments.

This issue of financial requirements and the ability of a plan to utilize either plan design option – shared financial requirements or separate but no more restrictive financial requirements – is discussed further in our response to question B.1. below but we note it here because a contrary interpretation would have a very significant and negative cost impact to plans and plan participants.

Section Endnotes:

1. Ringel, J.S., & Sturm, R. (2001). Financial burden and out-of-pocket expenditures for mental health across different socioeconomic groups: Results from Healthcare for Communities. *The Journal of Mental Health Policy and Economics*, 4, 141-150.
2. The Commonwealth Fund Biennial Health Survey 2005
3. McGuire, T. Financing Psychotherapy: Cost, effects and Public Policy (Cambridge, Mass. Ballinger Press 1981)
4. Taube, C. Estimating the Probability and Level of Ambulatory Mental Health Services Use Health Services Research 21, no.2 (1986): 321-340
5. Horgan, C., "The demand for Ambulatory Mental Health Services" Health Services research 21 no.2 (1986):291-319
6. Sethi, Rachel, Jee, Joanne (2006) Designing Employer Sponsored Mental Health Benefits. US Department of Health and Human Services publication
7. LoSasso, A.T., & Lyons, J.S. (2002). The effects of copayments on substance abuse treatment expenditures and treatment reoccurrence. *Psychiatric Services*, 53(12), 1605-1611.
8. Barry, C., Richard, F. The Cost of Mental Health Parity: Still An Impediment. Health Affair 25:623 – 634
9. Weissman, E., Pettigrew, K., Sotsky, S., & Regier, D.A. (2000). The cost of access to mental health services in managed care. *Psychiatric Services*, 51(5), 664-666.

10. . Lo Sasso, A.T., & Lyons, J.S. (2004). The sensitivity of substance abuse treatment intensity to co-payment levels. *The Journal of Behavioral Health Services & Research*, 31(1), 50-65.
11. LoSasso, A.T., & Lyons, J.S. (2002). The effects of copayments on substance abuse treatment expenditures and treatment reoccurrence. *Psychiatric Services*, 53(12), 1605-1611.
12. Simon, GE, Grothaus, ML. Impact of Visit Copayments on Outpatient Mental Health Utilization by Members of a Health Maintenance Organization. Am J. Psych 1996, 153:331-338

The MHPAEA does make changes to the application and use of copayments and deductibles. The MHPAEA states that financial requirements for mental health and substance use disorder services must be no more restrictive than the "predominant" financial requirement applied to "substantially all" medical and surgical benefits. The MHPAEA defines "predominant" to mean "the most common or frequent of such type of requirement" as applies to "substantially all medical and surgical benefits". The interpretation of this language could have a wide range of effect on the cost to the plan and plan participants.

One interpretation of this section of the MHPAEA would require that each type of financial requirement (i.e., deductible, copayment, and coinsurance) for mental health or substance use disorder benefits could only be a single amount across the board – regardless of the mental health specialty or level of care involved – as the "predominant" requirement to be compared for parity purposes to the "predominant" financial requirement (i.e., deductible, copayment, and coinsurance) under the medical and surgical benefits of the plan due to the use of the term "substantially all." This would necessitate a significant change to the current practices of plans. This interpretation does not account for the fact that plans apply varying dollar amounts within each type of financial requirement (i.e., deductible, copayment, and coinsurance) for medical and surgical benefits in order to reflect the medical specialty, level of care, and cost of care involved. The MHPAEA could theoretically be interpreted to prohibit the plan from doing likewise for mental health or substance use disorder benefits, which would be a radical departure from current, widely accepted plan design and plan administration practices. This would create a striking and vast negative impact on health care costs for plans and plan participants.

To illustrate this point using copayments, medical and surgical benefits utilize a range of copayment amounts depending on the type of service and/or level of care. For example, a plan design may provide a design where an office visit to the primary care physician (PCP) has a $15 copayment, a visit to a cardiologist has a specialty copayment of $35, a $100 copayment is applied to an emergency room visit, and a $250 copayment is assessed per admission for inpatient hospital care. Similarly, plans currently apply varying copayment amounts for mental health or substance use disorder benefits as well, depending on the type of service or level of care. However, the MHPAEA might be construed, as noted above, to require that there be only one single financial requirement applied to all mental health or substance use disorder benefits because the law requires the application of the "predominant" copayment applicable to "substantially all" medical and surgical benefits. The MHPAEA does not contain language that addresses the variances that exist for copayments based on the type of service or level of care involved.

Thus, using the example above, the $15 copayment could be applied to all mental health substance use disorder services admission at a inpatient facility, irrespective of type or level

of service in contrast to the financial requirements assigned to a type and/or level of care that is similar to medical services (i.e. $250 copayment for a mental health inpatient admission.). This could result in the plan being left to collect an inpatient admission copayment of only $15, since PCP visits are arguably the most "predominant" service utilized under medical and surgical benefits and therefore the copayment for PCP visits will be the "predominant" financial requirement applied to "substantially all" medical and surgical benefits. This result would increase plan costs substantially and create significant a disparity between the administration of medical and surgical benefits and mental health and substance use disorder benefits that is directly contrary to the intent of the MHPAEA.

The MHPAEA supports parity between mental health and substance use disorder benefits on the one hand and medical and surgical benefits on the other in a manner that takes into account the comparison of benefits that allows for the varied levels of care and treatment types, e.g. inpatient to inpatient and outpatient to outpatient utilized by both medical and surgical as well as mental health and substance use disorder benefits.

This ambiguity, and the cost impact of the interpretation of this ambiguity, with respect to the "alignment" of benefits for parity purposes also arises in the context of determining which medical and surgical copayment within the traditional outpatient level of care compares between medical and surgical benefits and mental health and substance use disorder benefits. It is extremely common for medical and surgical outpatient benefits to have differentiated copayments based on whether a provider is primary care provider or a specialty provider (e.g. cardiologist, gastroenterologist etc.). There are logical clinical reasons and policy arguments to support a plan's choice to align the mental health and substance use disorder outpatient copayment to the medical and surgical benefits' primary care or specialty care copayment. There could be cost differentials to either the plan or the participants depending on which category of medical office visits are used for alignment and parity of the mental health and substance use disorder outpatient copayment. Below is a cost illustration of the difference between aligning the outpatient mental health and substance use disorder benefit copayment to the medical and surgical benefit primary care or specialist outpatient copayment.

Cost Illustration for Aligning the mental health and substance use disorder outpatient copayment to primary care instead of to specialty care.

Assumptions for Purposes of Illustration:

- 100,000 plan participant group
- Total mental health and substance use disorder claims cost = $4.50 pmpm[1]
- In network outpatient utilization rate of 500 visits/1,000 group plan participants = 50,000 visits for this 100,000 plan participant group
- Specialist copayment = $35
- Primary care copayment = $20
- Average number of mental health and substance use disorder office visits per treatment episode = 8 office visits
- Office visit for psychotherapy once/week

Cost for PLAN if mental health and substance use disorder copayment is mapped to:

- Primary care
  - $1,000,000 ($20 copay/visit x 50,000 visits/year)
- Specialty care
  - $1,750,000 ($35 copay/visit x 50,000 visits/year)
- Cost to plan (difference between specialty copayment and primary copayment total) = $750,000
- PMPM Cost difference between aligning to Primary care versus specialty care = $0.63 pmpm or a 13.9% cost increase

Cost for individual PLAN PARTICIPANT per treatment episode:

- Copayment if mental health and substance use disorder outpatient copayment is aligned to medical primary care copayment - $20 X 8 = $160/8weeks
- Copayment if mental health and substance use disorder is aligned to medical specialty care copayment $35 X 8 = $280/ 8 weeks
- Cost difference to plan participant = $120/ 8 weeks

1. PMPM pricing is not necessarily reflective of typical mental health and substance use disorder benefit cost but was used for ease of illustration.

From the illustration above it is clear there is a cost impact for either the plan and plan participants based on the alignment of outpatient copayments as between primary care and specialty care. There are many plan changes that can have an impact on plans and plan participants the issue of aligning mental health and substance use disorder financial requirements, in this case outpatient copayments, is one with significant ramifications in isolation, let alone in combination with other parity changes that must occur. As discussed in section B.2 below, we would recommend this issue of alignment of financial requirements, and treatment limitations, be addressed to bring clarity and a level of flexibility and choice by plans by defining how "predominant" financial requirements (and treatment limitations) are defined and how it is to be determined what is applicable to "substantially all" medical and surgical benefits.

The MHPAEA does require plans to alter their administration of treatment limitations. The MHPAEA will remove or minimize treatment limitations such as annual outpatient visit limits, yearly inpatient day limits, annual and lifetime treatment episode limits. The removal of these limits – which currently function as cost controls – will have significant impact on the cost of plans and cost to plan participants. While not all benefit plans utilize such limits, and their removal will be a benefit for members whose care may have been impacted by one or more limits in the past, overall the removal of limits will increase the cost of the plan and benefit coverage for all plan participants.

The magnitude of cost impact related to parity of financial requirements and benefit limits varies and is affected by a wide variety of variables such as plan size, utilization, etc. It is clear however that pre-parity plans with more restrictive treatment limitations (and/or

financial requirements) will experience greater cost changes as the result of parity requirements under the MHPAEA based on prior experience with state parity law changes.

In our experience with the implementation of state parity laws, plans with restrictive pre-parity visit limits (limits of ≤ 20 outpatient visits) and/or financial arrangements (e.g. high copayment levels such as $50 copayments) had mental health and substance use disorder benefit plan cost increases as high as 70%. These increases were the result of financial cost differentials between the pre-parity and post-parity design changes and utilization changes that resulted from those changes in limits. In some cases these increases were symptomatic of pent up demand for services[1]. Several studies have performed cost impact analyses of post state-level and federal employee parity implementation. The identified plan cost increases ranged from no significant increase to greater than a 4% increase in total plan cost.[2-8] These studies also consistently demonstrated that cost impacts were lower than those for plans with managed care than for those plans without managed care. The MHPAEA's passage was predicated on improving access and coverage for mental health and substance use disorder benefits and services at an affordable cost. The stakeholders agreed that this affordable cost meant there was a need for plans, in the absence of the more restrictive financial requirements and treatment limitations prohibited by the MHPAEA, to be able to applied managed care terms and conditions.

These landmark studies have certainly been a major contributor to the acceptance of parity legislation by plans and health insurance issuers. Even though the findings are encouraging they cannot directly project the cost of implementing the MHPAEA of 2008. None of the studies, due to the absence of comparable state level legislation on this point, included in their analysis the cost associated with the extension of parity of financial requirements or treatment limitations to out-of–network services as is required in MHPAEA.

<u>The MHPAEA does impact the Out-of-Network (OON) benefits plans offer</u>. The requirement that plans must offer mental health and substance use disorder OON benefits if they offer medical and surgical benefits OON will require plans and health insurance issuers to offer OON mental health and substance use disorder health benefits to members who did not previously have such a benefit in many cases. OON services are challenging to administer for plans and health insurance issuers because of the difficulties in controlling the quality of the services and in coordinating the care.

OON services have long been an area of greater cost for plans (OON reimbursement rates typically exceed in-network negotiated discounted reimbursement rates) and plan participants (patients can be balance billed the difference between plan or health insurance benefit levels and actual provider charges) due to, in part, a lessened ability of plans and plan administrators to manage utilization of services and quality of services. This is because OON providers are not contractually obligated to respond to requests for information necessary for the plan to conduct utilization review, case management or quality-of-care reviews. Thus, the expansion of OON benefits coupled with the need for parity of treatment limitations and financial requirements applied to those OON services will be a driver of higher OON utilization and thus higher cost to plans and plan participants. Quantifying the

cost impact of OON parity benefit changes is difficult because there is no direct comparable experience upon which to base such estimates

The MHPAEA does impact state mental health legislation. Another area of potential high cost impact lays in the possibility for federal parity preemption of state mental health legislation, particularly laws mandating coverage of autism benefits. Currently eleven states have passed legislation mandating coverage for specific treatments of Autism Spectrum Disorder. These laws, with one exception, all include dollar and/or age limits for the mandated services.

Some of these autism mandates include mandates for particular treatments, such as Applied Behavioral Analysis (ABA) which is an intensive educational/behavioral rehabilitative approach focused on building skill, learning and behavior modification. Services are offered at least for 20 hours per week and can extend over several years depending on the age and the complexity of the child's condition. Several actuarial analyses done by states and by United Behavioral Health have projected the increased cost to plan participants to be any where from $0.29 per member (or plan participant) per month ("pmpm") to $4.59pmpm [8-11]. Variability of cost is based on condition prevalence, distribution of case severity, treatment access (limitation of experienced providers), wide variation in service rates ($25-$75/hour/child for ABA implementation) and the variability amongst ABA therapists in application of these techniques. Despite the variability of projected cost of autism services, it is clear that the cost impact is greater for the treatment of Autism Spectrum Disorders than for other benefits for children. Whitworth and Hussein demonstrated a significantly higher median total healthcare cost for children with autism than for those with asthma and diabetes for example (autism - $2,103.58 vs. $850.27 and $1,605.20 respectively).[12] The impact from autism relates both to treatment limitations and financial requirements as state laws have included both types of limitations on these mandates due to concerns about the very significant cost of these services.

The analysis of the potential cost impact of autism legislation is difficult. The passage of autism legislation is a relatively recent phenomenon and the various mandates contained within these laws do vary considerably. There is little experience to date to demonstrate with any accuracy the actual costs of these mandates. For these reasons, state legislatures while supporting these mandates have included treatment limitations and financial requirement limitations on these mandated services to protect against unpredictable and catastrophic costs to plans. Thus, the state autism mandates include defined financial requirements and treatment limitations such as annual dollar maximums and age limits as a mechanism to manage the cost of such mandates to plans and plan participants.

There is the potential for the MHPAEA to eliminate the cost controls that states have included in their mandates for autism coverage. The preemption, or non-preemption, of the financial requirements and treatment limitations provided as part of these coverage mandates could be a tipping point for plans in deciding whether to cover mental health and substance use disorders because the inclusion of these autism mandates without the financial requirements and treatment limitations provided for by state laws represents an open-ended financial exposure for the plan and plan participants. We have seen self-funded plans who

wished to cover benefits for Autism Spectrum Disorders decline to offer such coverage due to potential federal preemption under the MHPAEA and the uncertainty of highly unpredictable costs given lack of evidence and data to project the costs associated with this treatment and the associated utilization. This presents a potential area of conflict between the MHPAEA and state law which gives rise to the need for clarification of preemption of state law by the MHPAEA. Autism is just one example of a state law issue that may be addressed by the MHPAEA preemption provision but it is certainly not the only such example. This topic of preemption and the interplay of the MHPAEA and state law is addressed further in our response to question B.2. below.

Section Endnotes:

1. Branstrom, R.B., & Sturm, R. (2002). An early case study of the effects of California's mental health parity legislation. Psychiatric Services, 53(10), 1215
2. Barry, C.L., Frank, R.G., & McGuire, T.G. (2006). The costs of mental health parity: Still an impediment? *Health Affairs*, 25(3), 623-634.
3. Goldman, H.H., Frank, R.G., Burnam, A., et al (2006). Behavioral health insurance parity for federal employees. *New England Journal of Medicine*, 354(13), 1378-1386.
4. Melek, S.P., Pyenson, B.S., & Fitch, K.V. An actuarial analysis of the impact of HR 1424: "The Paul Wellstone Mental Health and Addiction Equity Act of 2007." Milliman, Inc. July 5, 2007
5. Rosenbach, M., Lake, T., Young, C., et al (2003). Effects of the Vermont Mental Health and Substance Abuse Parity Law. U.S. Department of Health and Human Services.
6. Simon, GE, Grothaus, ML. Impact of Visit Copayments on Outpatient Mental Health Utilization by Members of a Health Maintenance Organization. Am J. Psych 1996, 153:331-338
7. Lu, C. Frank, R. Demand Response of mental Health Services to Cost Sharing Under Managed Care. The Journal of mental Health Policy and Economics. 11:113-125
8. A Study of Assembly Bill A-999; A Report to the New Jersey State Assembly by the Mandated Health Benefits Advisory commission Feb 2007
9. Cumming, T Public Actuary report to the Oklahoma House of Representatives Dec 2008
10. Cost analysis- SB1537 of 2008, Pertaining to Private Insurance Coverage for Autism Diagnosis and Treatment
11. United Behavioral Health Actuarial Analysis 2008
12. Whitworth, F. Hussein, M, Vanderpoel D., Direct cost of Treatment in Autism: Burden of Illness Abstract Academy health Meeting 2005; 22:abstract no. 3950

In summary, the MHPAEA will impact plans and plan participants in a variety of areas including issues of cost sharing, benefit plan design, and plan administration. Direct costs include expected higher costs for mental health and substance use disorder health services due to the required changes in benefit design and the very probable increased use of OON services. Indirect costs result from changes that arise under the MHPAEA such as the increased administrative burden to manage changes in financial requirements and likely increased utilization will result in increases to plan costs and premiums for plan participants.

Direct benefits of the MHPAEA will be: (1) to arguably give members increased access to services and (2) in some cases, for plans which now must offer an OON option, additional choice for individual plan participants seeking services and treatment. Indirect benefits include the potential for enhanced functionality for an individual plan participant with mental health and substance use disorder problems, both at work and home. These changes will positively impact all stakeholders – plan sponsors, plan administrators, health insurance issuers, plan participants and consumers, in terms of health, costs, and health benefits.

A. ***(ii) Are there unique costs and benefits for small entities subject to MHPAEA (that is, employers with greater than 50 employees that maintain plans with fewer than 100 participants)? What special consideration, if any, is needed for these employers or plans? What costs and benefits have issuers and small employers experienced in implementing parity under State insurance laws or otherwise?***

Small group benefit plans, as defined in this question, will be subject to all of the issues outlined in our comments in section A.(i) above. While these costs are not "unique" to these plans, small groups are particularly vulnerable to cost increase issues. In particular, these plans are more susceptible to the impact of "catastrophic cases" – meaning that one or two seriously ill members can have a dramatic impact on the costs of the overall plan given its small size. This is as true for mental health and substance use disorders as it is for medical and surgical cases. The impact of the changes discussed above in A.(i), and the resulting cost impacts, create an enormous pressure on these small groups with respect to the temptation to exclude mental health and substance use disorder benefits which are not limited by treatment limitations and financial requirements by simply providing no coverage for these conditions at all. This option would allow these small groups to control overall plan costs and the unpredictable (and potentially catastrophic) effect for the plan and its participants posed by the risk of these high cost cases. This risk is heightened with the plan's inability to utilize financial requirements and treatment limitations under the provisions of the MHPAEA.

Parity implementation costs in states where there are existing specific parity requirements mandated by state law vary depending on the extent of the particular state law's parity requirements. However, increases of up to 15% in annual mental health and substance use disorder benefits costs are not unusual. Experience has shown that in these circumstances small groups have tended to choose more restrictive policies – policies which have more treatment limitations and financial requirements – for mental health and substance use disorders benefits such as an annual 20 visit limit for outpatient treatment, an annual 30 day for inpatient treatment or a lifetime episode limit for substance use disorder treatment. These measures have been necessary in order to control plan costs and make the benefits affordable for all plan participants. The ability of small groups to do this will be virtually eliminated under the MHPAEA since these plans typically do not have and, in many cases, as a practical matter cannot have, restrictions of the same type on substantially all of their medical and surgical benefits. The MHPAEA will also put increased pressure on costs for these small groups if they have members who need specialized mental health and substance use disorder needs. Thus for the small group segment the loss of coverage for mental health and substance use disorder entirely is a potential consequence of the provisions of the MHPAEA.

In addition to the vulnerability of small groups to outlier catastrophic costs, these plans, by virtue of their size, experience wider variability in benefit costs from year to year. This variability may result in a plan qualifying for the cost exemption provided for under the MHPAEA in one plan year but not in the next. This fact, coupled with the administrative burden of applying for and obtaining the cost exemption under the MHPAEA and the fact

that the exemption is only good for a single plan year may also have the unintended consequence of these plans dropping coverage of mental health and substance use disorders altogether. The MHPAEA sets forth a clear outline of the cost exemption qualifications and process but to the extent the process can be accessible and administratively less burdensome for small groups we believe such a process would better serve the overall goals of the MHPAEA with respect to these groups.

A. ***(iii) Are there additional paperwork burdens related to MHPAEA compared to those related to MHPA 1996, and, if so, what estimated hours and costs are associated with those additional burdens?***

The MHPAEA is a much more extensive piece of legislation in terms of its impact on plans and health insurance issuers than the MHPA of 1996. The MHPAEA will significantly increase the paperwork required for plans and health insurance issuers with respect to recordkeeping, reporting to governmental agencies and third-party disclosures.

Typical steps that are necessary for plans to become compliant with the MHPAEA will generate a significant level of paperwork for recordkeeping purposes. For example, in order to document review and assessment of plan designs to ensure compliance with the MHPAEA, plans or plan administrators must compare their medical and surgical benefit plan offerings against their mental health and substance use disorder health plan offerings. In most plans, this involves multiple medical and surgical benefit options being compared against multiple mental health and substance use disorder benefit options. The comparison process often results in plan design changes and the creation of additional benefit plan offerings. These plan changes and new plan design offerings must be documented and communicated to all stakeholders – the plan participants, the plan administrators, applicable regulatory agencies etc. It is not possible to accurately estimate the specific impact in terms of hours or costs at this time but it must be noted that each plan must be reviewed and changes made and that generates significant record-keeping paperwork, third-party disclosure requirements and filings with governmental agencies to ensure compliance with the MHPAEA and other legal and regulatory filing and disclosure requirements.

Finally, with respect to reporting or filing with governmental agencies, clarification of the MHPAEA's cost exemption provision (see our response to question B.6. below) will have an effect. Depending on what the process is for reporting and filing paperwork required for a plan to claim the cost exemption, along with the required notifications to plan participants, there will be additional paperwork burden and cost associated with that particular element of the MHPAEA.

B. ***1. The statute provides that the term "financial requirement" includes deductibles, copayments, coinsurance and out-of-pocket expenses, but excludes an aggregate lifetime limit and an annual limit. The statute further provides that the term "treatment limitation" includes limits on the frequency of treatment, number of visits, days of coverage, or other similar limits on the scope or duration of treatment.***

Do plans currently impose other types of financial requirements or treatment limitations on benefits?

With respect to financial requirements, the MHPAEA very precisely defines "financial requirements" to include "deductibles, copayments, coinsurance, and out-of-pocket expenses." It does not set forth any language with respect to "other financial requirements". The definition of financial requirements does include reference to aggregate lifetime and annual limits which are addressed under the Mental Health Parity Act of 1996. Outside of these defined "financial requirements" and aggregate lifetime and annual financial limits there are no other financial requirements applied by plans that are addressed under the language of MHPAEA. Thus, the answer to this question is that there are no other relevant financial requirements as that term is defined under the MHPAEA.

With respect to "treatment limitations", it should be noted that plans and health insurance issuers do, in some cases, apply other types of similar treatment limitations – as that term is defined currently by the MHPAEA. The definition of "treatment limitation" in the MHPAEA includes "limits on the frequency of treatment, number of visits, days of coverage, or other similar limits on the scope or duration of treatment." Currently plans and health insurance issuers frequently will apply the types of treatment limitations specifically listed (e.g. number of visits days of coverage) and will in some cases also apply "other <u>similar</u> limits on the scope of duration of treatment". In answering this question, and considering proposed regulations, the treatment limitations to be considered must be <u>similar</u> limits on the scope or duration of treatment in order for the provisions of the MHPAEA to apply. The similarity of a treatment limitation for the purpose of the MHPAEA must have some time, duration or frequency element similar to the treatment limitations which the MHPAEA specifically lists such as number of visits or days of coverage.

For example, one additional limit we would consider falling within this definition but not specifically listed currently by the MHPAEA, is a limit on a number of episodes of treatment. For example, some plans and health insurance issuers currently limit the number of episodes of inpatient detoxification treatment available to a plan participant or insured to a certain specified number of episodes per lifetime.

How do plans currently apply financial requirements or treatment limitations to (1) medical and surgical benefits and (2) mental health and substance use disorder benefits?

Plans and health insurance issuers utilize financial requirements and treatment limitations both in medical and surgical benefits as well as mental health and substance use disorder benefits. There is a wide variety in the use and application of financial requirements and treatment limitations applied by plans and health insurance issuers due to the demands of the marketplace and wide variety in plan designs utilized by plan sponsors and insurance purchasers in meeting their varied objectives in offering, promoting, sponsoring and providing benefit plans.

Are these requirements or limitations applied differently to both classes of benefits?

In some cases yes and in other cases no. Currently most plans and insurance issuers apply some forms of both financial requirements and treatment limitations (as those terms are defined by the MHPAEA) to both classes of benefits – medical and surgical benefits on the one hand and mental health and substance use disorder benefits on the other. In some cases plans and health insurance issuers vary the application of financial requirements and treatment limitations between the two classes of benefits and in some cases plans and health insurance issuers plan designs are already designed such that there is no disparity between the application of financial requirements and treatment limitations between the two classes of benefits.

However, it typically has been more common to see greater restrictions placed on the mental health and substance use disorder benefit in terms of financial requirements and treatment limitations and it is for this reason that we supported passage of the MHPAEA. We have also come across examples of plans where parts of the mental health and substance use disorder benefit were more generous than the medical and surgical benefit because the employer wanted to encourage use of the mental health and substance use disorder benefit.

Do plans currently vary coverage levels within each class of benefits?

Yes. It is extremely common for plans and health insurance issuers to apply varied financial requirements and treatment limitations within a class of benefits – meaning medical and surgical benefits as one "class of benefits" and mental health and substance use disorder benefits as a second "class of benefits". Frequently plans and health insurance issuers will apply variances in benefit levels and in the application of financial requirements and treatment limitations on the basis of the level of care, type of treatment setting or type of care involved. The most notable and predominant levels of care are inpatient care and outpatient care. In addition, in many cases, plans and health insurance issuers often delineate a separation within each class of benefits between in-network benefits and out-of-network benefits and apply differing levels of financial requirements and treatment limitations to those sub-divisions within the class of benefits.

For example, a plan may provide in-network benefits for inpatient coverage of 80% coverage with 20% coinsurance for the plan participant but for in-network outpatient visits the coverage may be 100% after payment by the plan participant of a $20 copayment. That same plan for out-of-network benefits might only provide for out-of-network inpatient coverage of 60% with 40% coinsurance for the plan participant and for out-of-network outpatient coverage might only be 50% after payment by a plan participant of 50% coinsurance. Thus, plans typically vary coverage within a class of benefits based on in-network and out-of-network coverage and inpatient and outpatient levels of care.

In assessing compliance with the MPHAEA, plans and health insurers presume that the requirements of the MHPAEA will assess the "predominant" financial requirements and treatment limitations applicable to "substantially all medical and surgical benefits covered by the plan (or coverage)" <u>with respect to similar coverage.</u> Meaning the plan or health insurance issuer will ensure that in-network inpatient coverage financial requirements and treatment limitations for mental health and substance use disorder are aligned with the

predominant financial requirements and treatment limitations on in-network inpatient treatment for medical and surgical benefits and likewise for in-network outpatient coverage financial requirements and treatment limitations, etc. This presumption should be clearly articulated in the regulations with respect to the terms "predominant" and "substantially all" contained in the MHPAEA. We discuss the need for this clarification in detail in B.2. below.

B. 2. What terms or provisions require additional clarification to facilitate compliance?

Overall, the MHPAEA provides clear, defined application of rules with respect to treatment limitations, financial requirements and out-of-network coverage to ensure the objective of equitable treatment of mental health and substance use disorder benefits with those benefits provided for medical and surgical treatment. However, there are a number of areas where further clarity regarding the application of parity within the bounds of the legislative language would be of assistance to all stakeholders.

What specific clarifications would be helpful?

We believe the following specific clarifications are vital for all stakeholders..

Flexibility on Design of Financial Requirements:

The application of parity to plan financial requirements, including deductibles and out-of-pocket expense maximums is a critical component of the MHPAEA. It is essential that, in implementing this key element of parity, plan sponsors have the flexibility to design plans with either shared or separate deductibles and out-of-pocket expense maximums. A combined deductible or out-of-pocket expense limit would involve a single deductible or out-of-pocket expense maximum applicable to both the medical and surgical benefits and to the mental health and substance use disorder benefits. A separate deductible or out-of-pocket expense maximum would involve two "parallel" deductibles or out-of-pocket expense maximums – one applicable to the medical and surgical benefits and one applicable to the mental health and substance use disorder benefits. Separate deductibles and out-of-pocket expense maximums would be designed to meet the parity standard established by the MHPAEA – namely that the financial requirements applicable to mental health and substance use disorder benefits be no more restrictive than those applicable to comparable medical and surgical benefits.

The MHPAEA's plain language states that plans must ensure that "there are no separate cost sharing requirements that are applicable **only** with respect to mental health or substance use disorder benefits." (Emphasis added). The interpretation of this language is that a plan cannot have a financial requirement (deductible, copayment, coinsurance and out-of-pocket expense) for mental health and substance use disorders that it does not also have for medical and surgical benefits. That is, you cannot have a separate financial requirement that is applicable ONLY to mental health and substance use disorder benefits where the plan does not also have a comparable requirement applicable to medical and surgical benefits. This language of the MHPAEA does allow for separate and no more restrictive deductibles and out-of-pocket expense maximums.

It is necessary to read this language in context of the language of the whole paragraph. The language specifically states that financial requirements applicable to such mental health and substance use disorder benefits may be "no more restrictive than the predominant financial requirements" applied to the medical and surgical benefits. This language would be meaningless unless the law allowed for financial requirements that were separately applied to mental health and substance use disorder benefits because if separate requirements are not permitted then there is no basis or need to make the statement that financial requirements be "no more restrictive".

If the intent of the law was to prohibit separate cost sharing provisions, the use of the word "only" in the language would be meaningless – the language of the MHPAEA would simply prohibit separate cost sharing requirements period. In addition, we note that the Federal Employee Health Benefit Plan (FEHBP) Carrier Letter dated April 20, 2009 directs health insurance issuers (also known as "carriers") to implement the requirements of the MHPAEA and it states "expenses incurred for mental health or substance use disorders may be applied to the same medical and surgical deductibles and catastrophic limits or to separate deductibles and catastrophic limits so long as they are for the equivalent amounts." In addition, this interpretation would be consistent with the existing parity law requirements under the MHPA of 1996 which allows plans to apply annual and lifetime limits either by means of a combined aggregate limit for medical/surgical and mental health and substance use disorder benefits or through separate limits that are equivalent to, or no more restrictive than, those for medical and surgical benefits.

For these reasons, we strongly recommend that the regulations allow for, and clearly articulate, that plan sponsors have the flexibility to design or select plans (or coverage) which provide valuable mental health and substance use disorder benefits, in parity with medical and surgical benefits, using either combined or separate, but no more restrictive, financial requirements. This range of design options within the framework of the MHPAEA is essential to encouraging mental health and substance use disorder coverage and keeping such coverage affordable for all stakeholders.

Lastly, we strongly believe where plans choose to implement combined financial requirements, it would support health care reform goals of simplification and cost-control, if the necessary data exchange interfaces (discussed above in our response to A.i.) were subject to standard industry wide formats and coding.

Management of the Benefit:

The law clearly was intended to allow for the management by plans of the mental health and substance use disorder benefits. The MHPAEA amends the construction clause in Section 712 of ERISA which contains language which states "Nothing in this section shall be construed…" The MHPAEA then adds to that clause the language "…in the case of a group health plan (or health insurance coverage offered in connection with such a plan) that provides mental health or substance use disorder benefits, as affecting the terms and conditions of the plan or coverage relating to such benefits under the plan or coverage,

except as provided in subsection (a)" (*Emphasis added*). This means that the only terms and conditions to which the law applies are the provisions for parity of financial requirements, treatment limitations and out-of-network coverage defined by the MHPAEA. The location of this provision in the law was purposeful and was specifically placed where it was so that it falls outside of the scope of the parity provisions. This was done so that the benefits would not be required, with respect to other terms and conditions of the plan, to be managed in the same way as the medical and surgical benefits, except for the financial requirements, treatment limitations and out-of-network coverage requirements. This was done in recognition of the very real differences between the two classes of benefits.

Management of the benefit is a critical component in plan administration for keeping the cost of the MHPAEA requirements in line with the assumptions and projections utilized by the Congressional Budget Office (CBO) in their analysis of the MHPAEA. Without the ability to uniquely manage the mental health and substance use disorder benefit costs with other plan terms and conditions that are not addressed by the MHPAEA, costs will increase substantially over the estimates done by the CBO. (See our response to A.(i) above for additional discussion on this issue).

The federal government in its provision and administration of mental health and substance use disorder benefits (including coverage purchasing decisions) has recognized the need for different terms and conditions and benefit management for mental health and substance use disorder benefits. For example, the Department of Defense TRICARE program requires pre-certification and concurrent review for non-emergency admissions to psychiatric and residential treatment facilities and for outpatient visits that go beyond a pre-determined number of visits. TRICARE does not uniformly apply these same requirements across medical and surgical services. Additionally the Office of Personnel Management (OPM) has recognized, in FEHBP's implementation of the MHPAEA, that "plans may manage care through referrals, prior authorization, treatment plans, pre-certification of inpatient services, concurrent review, discharge planning, case management, retrospective review, and disease management programs." (See FEHB Program Carrier Letter, Letter No. 2009-08 dated April 20, 2009).

Accordingly, we believe the regulations should clarify and reinforce that the MHPAEA does not require parity in all aspects of plan terms and conditions, just those elements specifically addressed in the MHPAEA – namely financial requirements, treatment limitations and out-of-network coverage.

Definition Clarification: "Predominant" & "Substantially All":

As noted previously, the MHPAEA requires that the financial requirements applicable to any mental health or substance use disorder benefits provided by the plan must be no more restrictive than the "predominant" financial requirements applied to "substantially all" medical and surgical benefits covered by the plan. The MHPAEA goes on to state that the "predominant" financial requirement means "the most common or frequent of such type of financial requirement." Therefore, the MHPAEA could be interpreted to require that each type of financial requirement (i.e., deductible, copayment, and coinsurance) for mental

health or substance use disorder benefits can only be a single amount across the board -- regardless of the mental health specialty or level of care involved.

As a result of this ambiguity, the definition of "predominant" needs further clarification, as we do not believe the intent of the MHPAEA was to eliminate the plan's ability to apply varying financial requirements (such as copayments and coinsurance amounts) based on the level of care provided as is common practice today. We believe the intent of the MHPAEA was for financial requirements applicable to mental health or substance use disorder benefits provided by a plan to be no more restrictive than the "predominant" financial requirement applied to similar levels of care for the medical and surgical benefits covered by the plan. This interpretation permits each type of mental health or substance use disorder benefit to be compared to its medical and surgical benefit counterpart for purposes of determining the applicable financial requirement and ensure compliance with the MHPAEA. Similarly, the term "substantially all" requires clarification as there is no definition of how "substantially all" is to be measured or assessed by plans.

The proper interpretation would be to allow outpatient mental health or substance use disorder benefits to have a copayment and coinsurance that is no more restrictive than the "predominant" copayment and coinsurance for similar medical and surgical benefits. Inpatient mental health or substance use disorder benefits would have a copayment and coinsurance that is no more restrictive than the "predominant" copayment and coinsurance for similar inpatient medical and surgical benefits and likewise for outpatient benefits. This same methodology would apply to other levels of care as appropriate and to distinctions between in-network and out-of-network benefits.

Accordingly we urge you to clarify this matter in the final regulations in a manner that supports this intended interpretation. The clarification should state that for purposes of parity compliance the "predominant" requirement be the most common or frequent type of such requirement <u>with respect to the similar coverage within the class of benefits, e.g. comparing inpatient mental health and substance use disorder requirements to inpatient medical and surgical requirements</u>. The term "substantially all" should likewise be defined with respect to similar coverage within the class of benefits.

<u>Definition Clarification: "Financial Requirements" & "Cost Sharing Requirements":</u>

Section 512(a)(1) of the MHPAEA requires that the "financial requirements applicable to such mental health or substance use disorder benefits are no more restrictive than the predominant financial requirements applied to substantially all medical and surgical benefits covered by the plan (or coverage), and that there are not separate cost sharing requirements that are applicable only with respect to mental health or substance use disorder benefits."

We note that the MHPAEA defines "financial requirement" as including "deductibles, copayments, coinsurance and out-of-pocket expenses" but the MHPAEA contains no definition of "cost sharing requirements." The language of the section, as currently written, cannot be fully and clearly interpreted and applied absent clarifying regulations specifically defining "cost sharing requirements."

The defined term “financial requirements” already includes those elements which are considered within the industry to constitute cost sharing mechanisms – namely deductibles, copayments, coinsurance and out-of-pocket expense requirements. We believe the term “cost sharing requirements” is redundant to the existing defined term “financial requirements” since there is nothing in the industry identified as a cost sharing requirement that is not already listed in the definition of “financial requirement” provided in the MHPAEA.

Accordingly, we believe the regulations should confirm that the term “cost sharing requirements” has the same definition as “financial requirements.”

Definition Clarification: “Treatment Limitation”:

In contrast to the definition of “financial requirement,” which lists those specific plan design elements which constitute “financial requirements” without any undefined terms, the definition of “treatment limitation” contains the undefined phrase “or other similar limits on the scope or duration of treatment,” which would benefit from clarification.

We believe that examination of the already enumerated types of limitations included in the definition of treatment limitations coupled with the language “or other similar limits on the scope or duration of treatment” provides a framework upon which the regulations can, and should, build in terms of providing a clear, unambiguous definition of those plan design elements which constitute “treatment limitations” which must comply with the parity requirements of the MHPAEA. As previously discussed above, in our response to item B.1., the treatment limitations to be considered must be similar limits on the scope or duration of treatment in order for the provisions of the MHPAEA to apply. The “similarity” of a treatment limitation for the purpose of the MHPAEA must have some temporal, frequency or durational aspect similar to the specific enumerated treatment limitations which the MHPAEA already lists in the definition of “treatment limitation” such as number of visits or days of treatment.

We do not believe it was the intent of the legislation, nor does the actual language of the law support, inclusion of things like evidence based treatments as a “similar limit on the scope or duration of treatment”. Limitations on treatment types are not “similar” to limitations on the number of visits or days of coverage. In addition, the definition of mental health benefits states that services for mental health conditions are defined under the terms of the plan and in accordance with applicable federal and state law (i.e. the plan decides what services, or treatments, it covers – which typically are evidence based treatments that are determined to be medically necessary). Also, the medical and surgical side does not require coverage of all evidence-based treatments. This is another provision that could result in increased costs if the regulators decide to go against the intent of the law and require coverage of all evidence-based treatments.

Therefore, the regulations should clarify that the term “other similar limits on the scope or duration of treatment” includes only those elements of a plan design which limit the

treatment in terms of time, frequency or duration. As previously stated, the only addition we can think of that would be a "similar limit on the scope or duration of treatment" is limitations on the number of episodes of treatment and we suggest that this category be added to the list of treatment limitations.

Implementation & Enforcement:

The MHPAEA stipulates that regulations will be promulgated by October 3, 2009. The guidance and clarifications contained within these regulations will not be timely enough for many plans with an implementation date of January 1, 2010 (or earlier). These plans make plan design decisions and changes well prior to January 1 to ensure that communication of changes to plan participants, enrollment and implementation processes for plan changes can occur with an efficient and seamless administration of benefits. For example, it is common for plans to require their members to choose a health plan with a January 2010 start date in the prior October, and so regulations promulgated by October 3, 2009 will be too late to provide guidance for plans such that the clarifications can be accounted for in plan designs and plan disclosure materials necessary for plans and participants to make informed plan enrollment choices. The quantity and depth of comments submitted in response to the RFI is evidence of the need for clarification and in its absence plans are making decisions using good faith interpretations of the MHPAEA.

Accordingly, we request that if a plan implements a plan design based on a good faith interpretation of the provisions of the MHPAEA as set forth in the statute without the benefit of being able to review and implement the regulations, then the plan should be exempt from any enforcement action and monetary penalties for non-compliance with the MHPAEA if it is later determined that the plan is not fully compliant with the parity law due to the regulations.

Furthermore, any changes that are required to make the benefit plan compliant with the parity law should not be required to be implemented in mid-year but should be deferred until the start of the next plan year. Otherwise, changes to the plan would be onerous, costly, and confusing for plan participants. Furthermore, state regulatory agencies responsible for review and approval of health insurance coverage do not have the capacity to rapidly re-review and approve plans in mid-year. This sort of provision for good faith compliance efforts by plans and health insurance issuers would be similar to allowances made in the effective date, implementation and enforcement of other federal regulations such as the privacy regulations promulgated under the Health Insurance Portability & Accountability Act (HIPAA).

Guidance on Preemption of State Laws:

We would request that the regulation provide clarification with respect to the relationship between state and federal laws with regard to parity. There are state-specific mandates regarding the treatment of mental health and substance use disorder problems (e.g. state mandates regarding length of stay, autism mandates etc.) and it is not clear how these mandates relate to the federal parity law and whether such provisions may or may not be

preempted by the MHPAEA. We do know that the intent of the parity law was to not preempt state coverage mandates.

Specifically, we would request: (1) further clarification and definition of the preemption language of the MHPAEA and (2) clarification on how a plan or health insurance issuer may obtain an advisory opinion or guidance in some other form with respect to particular state law interactions with the MHPAEA.

Application of the MHPAEA to particular types of plans:

We request clarification with respect to which entities are subject to the MHPAEA. It is our understanding that the law applies to Medicaid Managed Care plans; however, we have received questions regarding this interpretation so we are seeking clarification that the law does indeed apply to Medicaid Managed Care plans.

In addition, we would request clarification with respect to the application of the MHPAEA to Medicare plans, including both Medicare Advantage and Medicare Supplement plans and coverage.

Application of the MHPAEA to Employee Assistance Programs (EAP):

It is also our understanding that the law does not apply to Employee Assistance Programs (EAPs) and we would request specific clarification in the regulations confirming this as well. The law applies to group health plans (or health insurance coverage offered in connection with such plans) that provide both medical and surgical benefits and mental health or substance use disorder benefits. EAPs do not provide medical and surgical benefits and therefore, based on a reading of the plain language of the MHPAEA, we do not believe that the law applies to them. Furthermore, EAPs are most often sold as separate plans and are intended to provide short-term mental health and substance use disorder benefits for assessment and evaluation leading to appropriate referrals for treatment when necessary.

B. 3.What information, if any, regarding the criteria for medical necessity determinations made under the plan (or coverage) with respect to mental health or substance use disorder benefits is currently made available by the plan?

Criteria for medical necessity determinations are currently made available to plan participants, beneficiaries and contracting providers upon request and, in some cases, as a matter of routine disclosure without the need for a request by the participant, beneficiary and contracting provider. The information disclosed may range, depending on the circumstances, from the specific criteria relevant to a plan participant or beneficiary's particular specific request for benefits to a broad disclosure of the complete set of medical necessity criteria for all benefits under the plan to a contracted provider in order to facilitate communication and understanding of plan and health insurance carrier protocols with respect to utilization review and care management processes.

This practice of disclosure is a result of market-driven demand by health care consumers and providers for transparency in the elements which define benefits available to plan participants, beneficiaries, and contracted providers. In addition, there are existing legal and regulatory disclosure requirements for plan and health insurance issuer benefit plan information including medical necessity criteria information. This transparency and the prior development of federal and state law disclosure requirements and accreditation standards have driven plans and health insurance issuers to make the disclosure of medical necessity criteria utilized by plans and health insurance coverage purchased by such plans a routine function of the business of administering plan benefits. We fully support the need for such transparency and disclosures with the flexibility of achieving such disclosures electronically whenever possible and practical.

The MHPAEA codifies in plain language, the already existing best practices for disclosure of this information in accordance with existing law and current industry best practices and operating procedures prevalent in the health care industry as noted above.

For example, existing federal regulations under ERISA require that a plan (including insurance coverage purchased in connection with a plan) provide the plan's medical necessity criteria in the event that such criteria are utilized in the review and determination of a claim for benefits under the plan by a claimant – who can be a participant, beneficiary or contracted provider among others. The relevant provisions are included at 29 CFR 2560.503-1 "Claims Procedure". Specifically, the regulations require that a plan provide a participant, beneficiary or representative (often the provider) with both the specific provision of a plan relied upon in a benefit determination (see 29 CFR 2560.503-1(g)(ii)) as well as requiring disclosure of any internal rule, guideline, protocol or similar criterion (see 29 CFR 2560.503-1(g)(v)(A)). Thus plans and issuers have routinely provided to participants, beneficiaries and contracted providers the criteria utilized in making benefit determinations under the plan or insurance coverage.

In addition there are state insurance laws which require disclosure of medical necessity criteria in both the narrow context of a utilization review denial of a claim for benefits (similar to the federal ERISA requirement noted above) or in a broader context related to disclosure of plan benefit information. For example, in a more narrow context, Texas law requires disclosure of medical necessity criteria used in making a specific determination by a plan or health insurance issuer directly or through their utilization review agent (see 28 TAC 10.102I(3)). With respect to broad disclosure, take as one example, California law which requires disclosure of medical necessity criteria utilized by an insurer to the public upon request (see Calif. Ins. Code 10123.135(f)(2)(E)).

Currently health insurance carriers (including both insurers and managed care entities such as health maintenance organizations) who are accredited by organizations such as the National Committee on Quality Assurance (NCQA) or URAC (which is also known as the American Accreditation Healthcare Commission, Inc.) are also subject to this requirement as a matter of accrediting standards. Specifically, NCQA standards UM 2 and UM 7A require the disclosure of medical necessity criteria to participants and beneficiaries (UM 7A)

and practitioners (UM 2). URAC standard HUM 4 also addresses a disclosure requirement for utilization management requirements and procedures including medical necessity criteria.

To whom is this information currently made available and how is it made available?

The MHPAEA requirement clarifies, in very succinct fashion, that the criteria for medical necessity under the plan (or coverage) with respect to mental health and substance use disorder benefits, be made available by the plan administrator (or health insurance issuer). Specifically the MHPAEA requires that the criteria be disclosed "in accordance with regulations to any current or potential participant, beneficiary, or contracting provider upon request." (See 29 U.S.C. 1185a, as amended by the MHPAEA).

As noted above, the Congress specifically noted in the plain language of this section that such disclosures be made in "accordance with regulations". The language of the MHPAEA does not specify which regulations but as noted above, there are both federal and state disclosure requirements which are codified in existing regulations under ERISA and state law which are already in force and in practice by plans and health insurance issuers.

We presume Congress did not intend to disrupt or disturb existing specific disclosure requirements already in place under federal regulations and state law but rather sought in clear concise language to codify what, and to whom, disclosures must be made. This establishes a consistent "floor" of disclosure requirements that has already developed in practice due to existing state and federal regulations.

These existing regulations specify plan administrators and health insurance issuers must make disclosure of medical necessity criteria to a claimant – which is defined to include any plan participant or beneficiary as well as any party authorized to act on behalf of a claimant and specifically noting that providers can be authorized representatives of claimants. (See 29 CFR 2560.503 (a) and (b)(4)). State law requirements vary with respect to the definition of parties to whom plans and health issuers must provide disclosure of medical criteria – from the narrower requirement to notify and disclose to the beneficiary and the provider in Texas law to the broader member of the "public" requirement of California law (both of which are noted above). The MHPAEA requirement in this regard is clear – the disclosure must be provided to any current or potential participants, beneficiaries and contracted providers.

Are there industry standards or best practices with respect to this information and communication of this information?

Yes. The industry standards and best practices are an outgrowth of the combined market-driven need for transparency and existing federal, state and accreditation requirements for disclosure discussed above.

However, plans and health insurance issuers do face one constraint in the disclosure of medical necessity criteria. This constraint arises in the context of instances where a plan or health insurance issuer has licensed, from a third-party, medical necessity criteria which are

not the property of the plan or health insurance issuer. In the ordinary course of business, a plan or health insurance issuer may not further disclose or distribute such criteria without potentially infringing upon the intellectual property rights of the third-party who owns the criteria and/or violating the terms or provisions of a licensing agreement by which the plan obtained the medical necessity criteria from the third-party.

In order to comply with existing federal and state disclosure requirements currently, plans and health insurance issuers provide disclosure of a summary of the criteria as well as the source of the criteria without providing the actual medical necessity criteria so that they can comply with disclosure requirements but not be placed in violation of intellectual property rights or licensing agreement restrictions. This practice is necessary to meet disclosure requirements without violation of other legal requirements with respect to the content and ownership of these criteria. We believe this practice satisfies the MHPAEA requirement that a plan administrator or health insurance issuer "make available" the information and any regulations promulgated with respect to this requirement of the MHPAEA should reflect this practice as meeting the disclosure requirements for the medical necessity criteria under the MHPAEA language.

B. ***4. What information, if any, regarding the reasons for any denial under the plan (or coverage) of reimbursement or payment for services with respect to mental health or substance use disorder benefits is currently made available by the plan?***

Currently, pursuant to federal and state laws as well as accreditation standards, plans and health insurance issuers MUST provide the specific reason for any denial of a claim for benefits under the plan – including a denial of reimbursement or payment for services with respect to mental health or substance use disorder benefits.

The provisions of the MHPAEA require that: "The reason for any denial under the plan (or coverage) of reimbursement or payment for services with respect to mental health or substance use disorder benefits in the case of any participant or beneficiary shall, upon request or as otherwise required, be made available by the plan administrator (or the health insurance issuer offering such coverage) to the participant or beneficiary in accordance with regulations."

Plans and health insurance issuers currently comply with this and other, broader disclosure requirements under the existing federal ERISA claims regulations and state laws and accreditation standards which in many cases apply more broadly to any claim for benefits as opposed to simply requests for reimbursement or payment for services as specified in the MHPAEA.

To whom is this information currently made available and how is it made available?

The information is typically made available to the individual, or their authorized representative, as well as the provider involved in the claim for benefits or payment. For example, the ERISA claims regulations require that the notification to a claimant – which

may include a plan participant or beneficiary – be a written notice of a claim determination and must include the specific reason or reasons for an adverse determination. (See 29 CFR 2560.503-1(g)(1)i)).

In addition, there are state laws related to claims and utilization management which contain similar requirements. For example, Alabama law requires the issuance of a written notice for a retroactive denial of a claim issued to a provider to include the specific reason for the denial. (See Code of Ala. Sec. 27-1-17 (g)). This is one example among many different state laws which apply to claim and benefit denial notices to patients, beneficiaries and providers.

In addition, both NCQA and URAC accreditation standards explicitly require disclosure of the specific reason for a denial of benefits in writing to the patient and provider. NCQA utilization management standard UM 7 C with respect to notices of denials requires that the accredited organization provide to members and members' treating provider a written notice of denial which contains the "specific reasons for the denial, in easily understandable language." (See NCQA 2008 Utilization Management Standards). URAC also requires that the written notification of a non-certification decision include the principal reasons for the determination and requires that the principal reason must not be non-specific and be provided to the patient and attending physician or other ordering provider or facility rendering the services at issue. (See URAC Health Utilization Management Standards Version 6.0 – Standard HUM – 22).

Are there industry standards or best practices with respect to this information and communication of this information?

As noted above, the current industry standards and best practices are defined by federal and state law requirements as well as accreditation standards. The MHPAEA merely clarifies that these general practices and standards MUST be applied to any denial of reimbursement or payment for services with respect to mental health or substance use disorder benefits.

Again, as with the medical necessity criteria disclosure requirements discussed in question B.3. above, we presume Congress did not intend to disrupt or disturb existing specific disclosure requirements already in place under federal regulations and state law but rather sought in clear concise language to codify what and to whom such disclosures must be made. This establishes a consistent "floor" of disclosure requirements that has already developed in practice due to existing state and federal regulations. We believe these practices satisfy the MHPAEA requirement that a plan administrator or health insurance issuer "make available" the specific reason for a denial of reimbursement or payment for services and any regulations promulgated with respect to this requirement of the MHPAEA should reflect these practices as meeting the disclosure requirements for the specific denial rationale for any reimbursement or payment of services under the MHPAEA language.

B. 5. To gather more information on the scope of out-of-network coverage, the Departments are interested in finding out whether plans currently provide out-of-network coverage for

mental health and substance use disorder benefits. If so, how is such coverage the same as or different than out-of-network coverage provided for medical and surgical benefits?

Plans and health insurance issuers currently vary in the offering of out-of-network benefits for treatment of mental health and substance use disorders. Typically, the coverage for out-of-network benefits varies between the two classes of benefits – medical and surgical benefits, on one hand, and mental health and substance use disorder benefits on the other.

Plans and health insurance issuers classify and apply financial requirements and treatment limitations which are applicable to mental health and substance use disorder benefits in the same fashion as they do for in-network benefits. That is, plans vary coverage within the context of out-of-network benefits based on the type of coverage in terms of dividing inpatient and outpatient benefits.

Again, in assessing compliance with the MPHAEA, plans and health insurers presume that the requirements of the MHPAEA will focus on the "predominant" financial requirements and treatment limitations applicable to "substantially all medical and surgical benefits covered by the plan (or coverage)" with respect to similar coverage (see discussion in response to B.1 and B.2. above), meaning the plan or health insurance issuer will ensure that for out-of-network benefits, just as with in-network benefits, inpatient coverage financial requirements and treatment limitations for mental health and substance use disorder would be aligned with the predominant financial requirements and treatment limitations on inpatient treatment for medical and surgical benefits and likewise for outpatient coverage financial requirements and treatment limitations.

B. 6. Which aspects of the increased cost exemption, if any, require additional guidance?

In the case that a plan chooses to seek a cost exemption there needs to be additional guidance on what the process is for filing an exemption. Specifically, what forms and data must be documented and filed, what form should actuarial certifications take and what other information, if any, must be documented and filed. In addition, clarification of the standards to be applied by the applicable agencies for the review and response to such filings would be informative to stakeholders.

Would model notices be helpful to facilitate disclosure to Federal agencies, State agencies, and participants and beneficiaries regarding a plan's or issuer's election to implement the cost exemption?

Yes, we believe that model notices provided by the agencies would be helpful.

Conclusion

UnitedHealth Group appreciates this opportunity to provide you with our comments on the RFI for the MHPAEA. Should you have any questions regarding the information set forth in these

comments please do not hesitate to contact us. Thank you again for the opportunity and your time and consideration of the enclosed comments.

Sincerely,

Mitch Zamoff
Acting Chief Legal Officer

Appendix Materials

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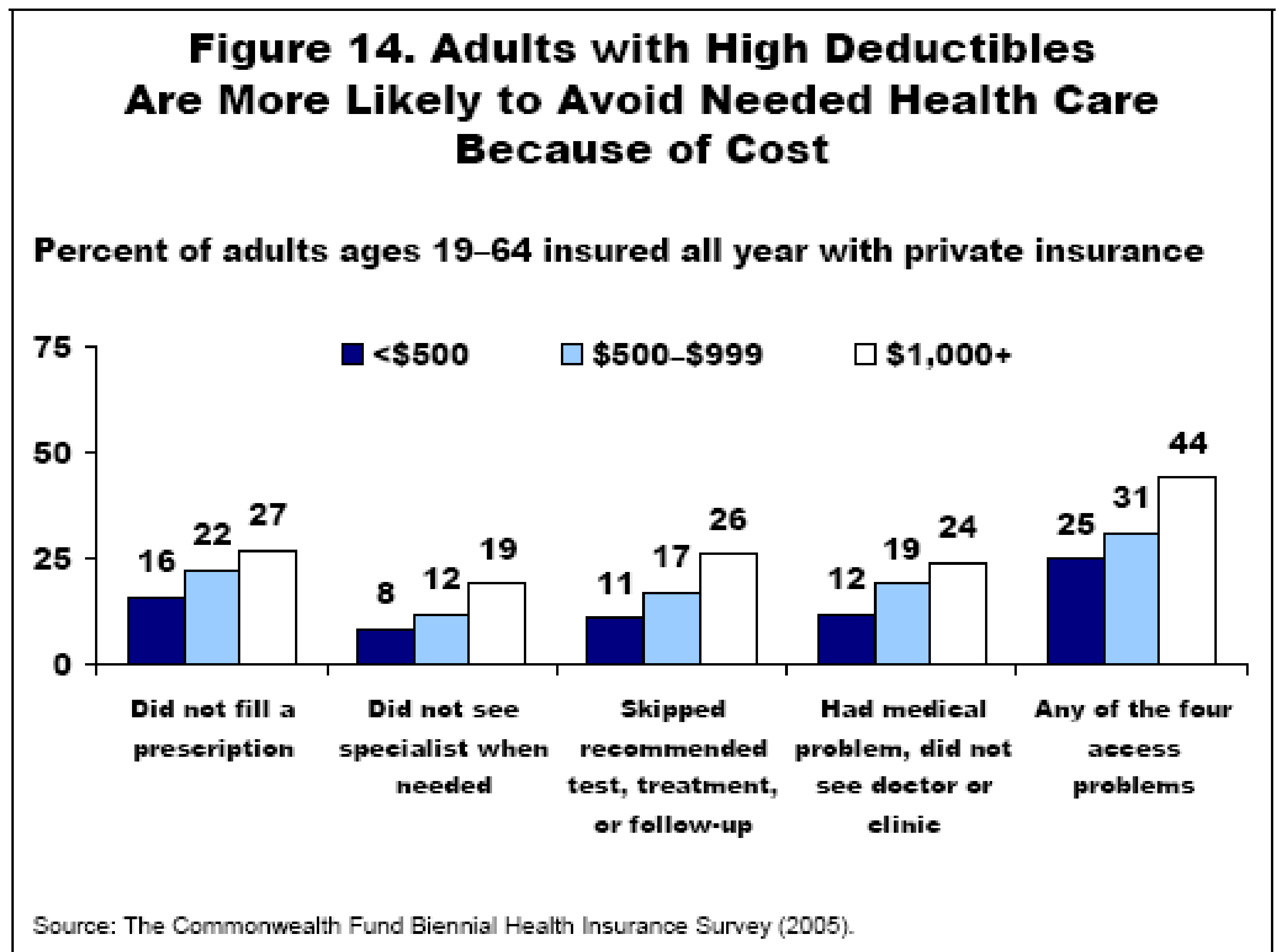
EXHIBIT 2
Evidence On Effects Of Mental Health Care Benefit Changes, 1998–2006

	H.H. Goldman et al. (2006)[a]	Bao and Sturm (2004)[b]	Rosenbach et al. (2003)[c]	Ma and McGuire (1998)[d]	W. Goldman et al. (1998)[e]
Research setting	FEHB	States with and without parity laws	State of VT parity law	Group Insurance Commission (GIC) of MA	Large group employer
Data source	FEHB claims data, 1999-2004	Healthcare for Communities	Claims from two large health insurers	GIC enrollment and claims data	Claims data from indemnity plans
Estimation methods	DD estimation	DDD estimation	Multivariate regression	Multivariate regression	Multivariate regression
Managed care	↑ in carve-out contracting; network design changes	Unclear	Introduction of a new carve-out contract in one of two large insurers studied (with network changes)	Introduction of a carve-out contract (with network changes)	Introduction of a carve-out contract
Probability of use	No change or ↓ in probability of use for 7 of 8 plans	No change (measuring easier/harder to get good-quality health care)	↑ in outpatient users for both plans; ↑ in inpatient users in one plan and ↓ in the other	↓ in outpatient use; no change in inpatient admissions (but shift to less intensive settings)	↑ in probability of any mental health care use; ↓ in probability of inpatient use
Level of use	–[f]	–[f]	↑ in outpatient visits for one plan and ↓ in the other; no change in inpatient use	↓ in outpatient visits per user and in inpatient length-of-stay	↓ in outpatient visits per user; ↓ in inpatient length-of-stay
Total spending per user	No change or ↓ in spending per user for all plans	–[f]	↓ in outpatient spending per user; ↑ in inpatient/partial hosp per user ($p < .10$)	↓ in price per outpatient visit; ↓ in price per inpatient day	↓ in average cost per outpatient session; ↑ in average cost per inpatient day
Out-of-pocket spending	↓ or no change in out-of-pocket spending per user in 6 plans and ↑ in 3 plans	–[f]	↓ in out-of-pocket spending	↓ in out-of-pocket spending	–[f]



- Figure 14 is taken from the Commonwealth Fund Biennial Health Insurance Survey (2005) National
- Survey of 4,350 individuals ages 19 – 64 years of age
- Focused on self reported impact of high deductibles on access to treatment