August 31, 2016

U.S. Department of Health & Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Sir/Madam:

Beacon Health Options (Beacon) welcomes the opportunity to submit comments and recommendations to the Mental Health and Substance Use Disorder Parity Task Force (Task Force).

Beacon is among the largest independent managed behavioral health companies in the world. The company serves 50 million people across all 50 states and the United Kingdom. Beacon serves employer, health plan, FEP, Medicaid, Medicare, and Exchange populations. Notably, Beacon has programs serving Medicaid recipients and other public sector populations in 28 states and the District of Columbia. In addition, Beacon provides services for 8.5 million military personnel, their family members, veterans and federal employees. Beacon is also the largest specialty payer for autism services in the country.

Mental Health Parity: We are All Stakeholders in a Common Mission

Managed Behavioral Health Organizations (MBHOs) such as Beacon have taken tremendous steps to support implementation of the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA). These efforts preceded MHPAEA final regulations,1 which were released in 2013, and continue today through working with employers, health plans, state Medicaid agencies, regulators, legislators, providers, behavioral health interest groups and advocates and others to further parity compliance. At the same time, Beacon works to provide the right level of care for consumers in an affordable manner, a goal compatible with parity compliance and consistent with broader clinical practice. According to a recent Health Affairs article, the largest share of health spending in this country is on mental disorders,2 and as such, more and better mental health/substance use disorder (MH/SUD) treatment is a must for our country to thrive. Beacon supports increased MH/SUD treatment, not only because of the societal and clinical imperative, but also from the business side; it allows Beacon to reach new patients who previously had no access to vital services. In this context, Beacon pursues the triple aim for healthcare delivery:

- Improving the patient experience of care (including quality and satisfaction);
- Improving the health of populations; and
- Reducing the per capita cost of health care.

As with any large piece of transformative legislation, much work still remains by regulators, payers, providers and public interest groups to aid consumers in their ability to understand their MH/SUD benefits and ensure that they receive the right type of individualized care. MHPAEA’s goals of non-discrimination and comparability with medical/surgical services are correct and laudable. As we know, however, from a clinical and common sense perspective, MH/SUD services and treatment are not amenable to a cookie-cutter approach when comparing to medical/surgical services and treatment.

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1 78 FR 68240 (MHPAEA final regulations).
2 See http://content.healthaffairs.org/content/early/2016/05/13/hlthaff.2015.1659.abstract.
Accordingly, Beacon proposes that the Task Force address the following topics:

1. Recognition of clinical differences between MH/SUD and medical/surgical services and treatment;
2. Issuance of clarifying guidance for non-quantitative treatment limitations (NQTLs);
3. Clarification of disclosure requirements to ensure that consumers receive the right level of information; and
4. Provision of additional tools for states to conduct consistent parity analyses.

**Parity is Not a Panacea for All MH/SUD Treatment Issues**

Parity is not the only issue vexing the MH/SUD system. Beacon sees shortages of MH/SUD treatment providers in many parts of the country, as well as a dearth of research and public and private funding for innovative MH/SUD treatments. Although questions regarding how best to effectuate certain facets of MHPAEA remain, parity in and of itself does not solve the myriad issues facing MH/SUD patients.

Of particular concern is a persistent misperception that if a payer’s (e.g., employers, health plans, state Medicaid agencies) utilization management (UM) practices for MH/SUD benefits were made public, it would reveal a systematic general discrimination against MH/SUD patients. Consequently, many stakeholders appear to believe that parity is akin to mandated, unlimited and unmanaged MH/SUD treatment. However, ignoring the importance of medical necessity through effective UM is fraught with peril because doing so disregards legitimate medical considerations, including being able to ensure:

- The appropriate level of care;
- Limited higher level of care resources are used for the most appropriate patients (moving patients who need less intensive services to more appropriate levels of care);
- The right amount of treatment, for the right duration;
- The use of evidenced-based practices;
- The coordination of care; and
- The coordination of discharge plans and follow-up treatment.

A focus on mandated treatment without any quality-focused, medical necessity-based UM will move care away from evidence-based practice and least restrictive setting protocols.

Parity is about non-discrimination and comparability—not matching MH/SUD UM approaches with medical/surgical ones in an identical way. While Beacon agrees that the mind/body treatment is essential, ignoring the differences between diseases of the brain and other illnesses is ill-advised. Although new treatments like Applied Behavioral Analysis (ABA) or Transcranial Magnetic Stimulation (TMS) may no longer be investigational/experimental for certain diagnoses, they are not necessarily as firmly established as longstanding medical/surgical treatments, such as insulin injections or asthma inhalers. ABA is in many ways in its infancy as it remains unclear why some children progress with the therapy while others do not. Comparing ABA to any other treatment in the entire panoply of medicine in the context of medical management does not make sense since no other therapy (medical/surgical or MH/SUD) requires one-on-one intense interventions for 40 hours a week for multiple months.

Likewise, private physicians are permitted to prescribe methadone to treat chronic pain, as distinguished from addiction. Federal regulations require that all methadone for the treatment of addiction be provided through programs licensed and monitored by the Food and Drug Administration (FDA), the Drug Enforcement

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3 See, e.g., Beacon’s White Paper on Integration at [http://beaconlens.com/wp-content/uploads/2016/02/Beacon-Whitepaper-FINAL.pdf](http://beaconlens.com/wp-content/uploads/2016/02/Beacon-Whitepaper-FINAL.pdf). Beacon looks to the evidence for the best approach to integrate behavioral and physical health care to improve the overall health of our members. Our extensive research points to the collaborative care model (CCM), pioneered by the AIMS Center at the University of Washington, as the best-in-class approach. For people with SMI, the paper demonstrates the need for integrating primary care expertise into special mental health settings, such as community mental health centers.

Administration (DEA), and state methadone authorities. Due to these requirements, methadone is by definition out of parity because of disparate regulatory treatment rather than discriminatory procedures by an MBHO.

Moreover, beyond UM techniques, there is also a misperception among certain stakeholders that, because more denials may exist on the MH/SUD side than on medical/surgical side within a category of benefits, an MHPAEA violation exists. Denial rates in and of themselves are not germane to an MHPAEA analysis.  

**Analysis of NQTLs**

As alluded to above, with regard to NQTLs, some stakeholders argue that patients with MH/SUD are not treated the same as patients with other chronic conditions and illnesses, such as cancer or diabetes. UM routinely occurs on the medical/surgical side and does so within the context of major provider organizations, such as hospitals. UM occurs because it is the right clinical approach in reviewing the medical necessity of a course of treatment or service for the patient's condition. Notably, CMS recently proposed prior authorization for Medicare home health services. Step-downs from inpatient to outpatient settings occur regularly on the medical/surgical side because it is medically appropriate to do so. Further, medical necessity determinations and cost containment are factors in UM decisions on the medical/surgical side.

The “predominant” and “substantially all” tests that apply to financial requirements and quantitative treatment limitations do not apply to a payer’s NQTLs. The MHPAEA final regulations require the application of a different test because NQTLs are not mathematical in nature. Many stakeholders refuse to accept this dictate and keep trying to argue that a mathematical component should be included in the compliance analysis. Rather, Beacon has argued that the analysis should involve a comparison of factors used in designing medical management techniques for both MH/SUD and medical/surgical benefits. Notably, while the MHPAEA uses a comparable and no more stringent test for NQTLs, it does not apply a mathematical component.

A key issue that arises upon conducting an NQTL compliance analysis concerns how a payer should conduct the NQTL comparability/stringency analysis. Does a plan use a one-to-one benefit comparison? Or is a plan supposed to look across the entire group of benefits? In a recent presentation, one public advocate offered the following comparisons as part of an MHPAEA analysis: Inpatient detoxification vs. inpatient appendicitis, giving birth or salmonella poisoning, and outpatient psychological vs. outpatient primary care visit for flu. Another public advocate...
compared psychiatry vs. oncology in its MHPAEA analysis. These comparisons are arbitrary and confusing. There is no directive that such interpretations are correct from either MHPAEA itself or the implementation regulations.

On the outpatient side, many medical/surgical benefits are generally subject to preauthorization, including: durable medical equipment, diagnostic imaging, home infusion therapy, cochlear implants, infertility treatment, and sleep apnea testing and treatment (CPAP). It would be incongruous and misleading to select a single benefit on the medical/surgical side to be used as the baseline for an NQTL comparison for a single benefit within any given classification. If that is the case, then comparing psychotherapy to CPAP treatment would allow for preauthorization before the first visits, which Beacon does not require. Rather, the goal should be a review of multiple benefits across the category, or linkage should occur based on similar characteristics and types of services.

For example, one grouping of services that exists in both the medical/surgical and MH/SUD outpatient classifications is “therapy visits.” “Therapy visits” are defined as treatment modalities or services that are dependent on the provider and patient interaction as the major form of treatment. This is in contrast to what are called “office visits” where the primary focus of the provider and patient encounter is diagnosis, assessment, development of a treatment plan, prescribing treatment and monitoring effect/side effects of the treatment that takes place outside of the encounter. “Therapy visits” characteristically have a higher frequency of visits for a treatment episode than “office visits.” Thus, MBHOs often use chiropractic treatment, physical therapy, occupational therapy, and speech therapy as comparators for routine outpatient behavioral health treatments.

On the inpatient side, a behavioral health unit admission for an adult alcohol detoxification may be approved with no concurrent review scheduled until the fourth day of admission. On the other hand, an inpatient admission for suicidal behavior may be approved for two days with a concurrent review conducted on the second day to assess current lethality and review the proposed treatment plan. A comparable example for a medical/surgical unit is an adult with chest pain who is admitted under observation status for further stabilization and evaluation including hydration, enzymes monitoring, and telemetry to further assess symptom severity and the need for more intensive treatment. A concurrent review is conducted the following day and further approval for continued stay dependent on the assessment findings and the recommended course of care. Thus, the specific linkage of acute admissions on the inpatient side is more apropos than linking non-conforming benefits, such as detoxification with giving birth.

Indeed, we believe that it is important to focus on whether group the health plan is applying clinically accepted MH/SUD protocols since clinical appropriateness is part and parcel of medical/surgical protocols. We suggest that the following example used in the MHPAEA final regulations govern any analysis:

A plan generally covers medically appropriate treatments. For both medical/surgical benefits and mental health and substance use disorder benefits, evidentiary standards used in determining whether a treatment is medically appropriate (such as the number of visits or days of coverage) are based on recommendations made by panels of experts with appropriate training and experience in the fields of medicine involved. The evidentiary standards are applied in a manner that is based on clinically appropriate standards of care for a condition.

In this Example…the plan complies with the rules…because the processes for developing the evidentiary standards used to determine medical appropriateness and the application of these standards to mental health and substance use disorder benefits are comparable to and are applied no more stringently than for medical/surgical benefits. This is the result even if the application of the evidentiary standards does not result in similar numbers of visits, days of coverage, or other benefits utilized for mental health conditions or substance use disorders as it does for any particular medical/surgical condition.\footnote{78 FR 68272.}
Beacon encourages the Task Force to recognize that differences do exist between behavioral health and physical health in order to ensure that the best quality, evidence-based care is being provided to consumers. Parity should not just be about the correct analysis being done; we should be asking whether this comparison results in good care for the patient. We request that the Task Force allow for differences to exist if the plan can justify why a difference in practice is better for the patient. One way to ensure that is to focus on the above example and reliance on panels of experts to make clinical determinations. Such an approach is more reliable than some advocates’ push for an overly rigid or imprecise benefit/service crosswalk approach of arbitrary comparisons.

Recent FAQ on Disclosure to Consumers

Beacon has concerns with the suggested MHPAEA disclosure framework per a recently released DOL/HHS/IRS FAQ. This recent subregulatory guidance implies that significantly more information needs to be disclosed to consumers than previously understood by Beacon in order to justify application of an NQTL. According to FAQ 9, in analyzing the use of an NQTL-like preauthorization, a group health plan must compile the following information:

- The specific underlying processes, strategies, evidentiary standards, and other factors (including, but not limited to, all evidence) considered by the plan (including factors that were relied upon and were rejected) in determining that the NQTL will apply to this particular MH/SUD benefit.
- Information regarding the application of the NQTL to any medical/surgical benefits within the benefit classification at issue.
- The specific underlying processes, strategies, evidentiary standards, and other factors (including, but not limited to, all evidence) considered by the plan (including factors that were relied upon and were rejected) in determining the extent to which the NQTL will apply to any medical/surgical benefits within the benefit classification at issue.
- Any analyses performed by the plan as to how the NQTL complies with MHPAEA.

The FAQ also suggests that studies, schedules or similar documents be collected to justify use of a particular NQTL.

For example, a plan may consider whether a preauthorization for ECT is allowable. ECT is a high-cost service with safety concerns most often administered in a hospital setting, requiring medical management akin to certain outpatient surgeries on the medical/surgical side. In preparing for the ECT procedure, the patient is not permitted to eat/drink prior to the procedure; anesthesia medication is applied via an IV inserted into a vein; a muscle relaxant is also given; electrodes monitor the patient heart (EKG), brain waves (EEG – electroencephalogram), and muscle movement in the foot (EMG – electromyelogram); the patient receives oxygen via a mask; and, after the ECT treatment, the patient is closely monitored by nurses in a recovery room for approximately 45 minutes following the procedure.

ECT does not always produce the desired outcome of symptom reduction. Safety concerns exist. Medical management reviews help determine whether ECT is effective or whether additional treatment strategies should be considered. Because prior authorizations are also generally required on all outpatient surgeries on the

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17 See [https://www.federalregister.gov/articles/2015/12/29/2015-32592/neurological-devices-reclassification-of-electroconvulsive-therapy-devices-intended-for-use-in](https://www.federalregister.gov/articles/2015/12/29/2015-32592/neurological-devices-reclassification-of-electroconvulsive-therapy-devices-intended-for-use-in). A draft rule under consideration at the Food and Drug Administration (FDA) notes that ECT has side effects and its long-term safety is unproven. Under the rule, physicians would have to monitor patients’ memory and cognitive skills before and during treatment with sensitive neuropsychological tests. The FDA has evaluated the risks to health associated with the use of ECT devices and determined that the following risks to health are associated with its use: Adverse reaction to anesthetic agents/neuromuscular blocking agent, adverse skin reactions, cardiovascular complications, cognition and memory impairment, death, dental/oral trauma, device malfunction, manic symptoms, pain/discomfort, physical trauma, prolonged or tardive seizures, pulmonary complications, skin burns and worsening of psychiatric symptoms. These risks underscore the need for preauthorization. Indeed, it is hard to understand why any consumer or provider would not want this service monitored and evaluated by insurers for medical necessity. The FDA received 2,040 comments on its draft rule before the public comment period closed in late March.
medical/surgical side, it appears that no MHPAEA violation exists. Both ECT and outpatient surgeries are high-cost, often with variable results and safety concerns.

Nevertheless, under the above-noted FAQ, merely stating “high cost” or “variability” or “safety” may not suffice as a sufficient MHPAEA disclosure. However, a plan may not have additional documented information or studies required by the FAQ beyond listing the above factors and description of concerns. ECT has been around since 1938, and many of the best practices surrounding it, including UM practices, were developed prior to adoption of the MHPAEA. The FAQ is unclear as to whether a plan would have to review and document existing literature regarding ECT and outpatient surgery to support the conclusion that such benefits are high-cost, have variable results, and incur safety concerns. Given the education-level and magnitude of clinical experts who would need to be engaged, the time and cost for such an undertaking would be vast for this one procedure alone.

Ultimately, it is unclear whether the FAQ disclosure open-endedness will improve patient care at a fair cost. Do consumers want such detailed information? It is Beacon’s belief that a more user-friendly analysis, in a readable, pithy format, would better serve consumers in their quest to ensure that MH/SUD benefit utilization management practices are not discriminatory.

Tools to Address Varying MHPAEA Interpretations of NQTL Compliance across States

Beacon is encountering disparate interpretations among MHPAEA state regulatory agencies. Beacon proposes that a more uniform approach regarding NQTLs should be instituted. Federal regulators should work to coordinate market conduct exams, state regulatory inquiries, attestations and questionnaires with state insurance regulators and the National Association of Insurance Commissioners.

Beacon’s Commitment to Parity Compliance

Beacon has guided more than 350 client organizations through parity alignment. Beacon developed a process guide and compliance readiness tool based on the Department of Labor review framework (http://www.dol.gov/ebsa/pdf/cagappa.pdf) and on our company’s experience in serving the behavioral health and substance use treatment needs of patients. Our review includes the following steps:

- Review summary plan documents of benefit descriptions;
- Review medical necessity criteria and medical policy;
- Review medical management program descriptions;
- Review network-related issues, including credentialing and reimbursement;
- Conduct discussions with group health plan administrator and medical/surgical plan regarding process for development and application of NQTLs;
- Document findings; and
- Review findings with stakeholders and recommend changes to benefits or practices (if any).

Beacon has been proactive in complying with MHPAEA and providing significant support to our clients in the form of materials and consultations. Beacon strives to innovative programs and create solutions that directly address the challenges consumers face today. Beacon’s approach to parity compliance embodies a commitment to consumers in order to ensure that they achieve healthier and more productive lives.

Conclusion

We are thankful for this opportunity to provide our views to the Task Force on Parity, and we thank participants for their dedication to a successful outcome for this Task Force. Beacon will continue to implement innovative programs that improve access to quality, affordable, and evidence-based behavioral health care. We will also continue to work with policymakers in removing barriers to further innovations and improvements for those
individuals with MH/SUD conditions. Should you have any questions, please feel free to contact me at jay.curley@beaconhealthoptions.com or (617) 476-1651.

Sincerely,

Jay Curley, JD
Executive Vice President of Corporate Affairs,
Chief of Staff to the CEO
Beacon Health Options