



June 22, 2018

U.S. Department of Labor
200 Constitution Avenue, NW
Washington, D.C. 20710

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

U.S. Department of Treasury
1500 Pennsylvania Avenue, NW
Washington, D.C. 20220

To Whom It May Concern,

Beacon Health Options (Beacon) welcomes the opportunity to submit comments and recommendations on the Department of Labor, Department of Health and Human Services, and Department of Treasury's (the "Tri-Departments") request for comment on the "Proposed FAQs About Mental Health and Substance Use Disorder Parity Implementation And The 21st Century Cures Act Part 39" and the "Revised Draft MHPAEA Disclosure Template," due by June 22, 2018. Although not explicitly open for public comment, Beacon is also providing comments on the "Self-Compliance Tool for the Mental Health Parity and Addiction Equity Act ("MHPAEA")."

Background

Beacon is among the largest independent managed behavioral health companies in the world. The company serves 40 million people across all 50 states. Beacon serves employer, health plan, FEP, Medicaid, Medicare, and Exchange populations. Notably, Beacon has programs serving Medicaid recipients and other public sector populations in 25 states and the District of Columbia. In addition, Beacon manages services for 5.4 million military personnel, and their family members. Beacon is also among the largest specialty payers for autism services in the country.

Beacon has taken significant steps to support implementation of MHPAEA. These efforts preceded MHPAEA final regulations, 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.

In these comments, Beacon discusses the need for refined guidance for non-quantitative treatment limitations (NQTLs), including reimbursement and the appropriate level and detail for the disclosure of MHPAEA information.

NQTLs

Legal framework

The granular direction of the NQTL guidance is confusing and burdensome, which does not serve to improve consumers' behavioral health treatment and access. We believe that an increased burden from the draft guidance will result in significant administrative costs with little value to the public. Specifically, the information set forth in the Self-Compliance Tool will require plans to produce or review large quantities of technical information, such as comparative effectiveness studies, clinical trials, professional protocols, published research studies, thresholds for evidentiary standards, such as "two standard deviation higher in total cost than the average cost per episode 20 percent of the time in a 12-month period", and internal claims database analyses, among other examples. We are concerned that this level of detail in the Self-Compliance Tool goes far beyond what is required in the law. The NQTL analysis provided in the Self-Compliance Tool changes the analysis as described in the regulation by introducing new requirements not referenced in the regulatory text nor discussed in previous parity guidance. For example, the Self-Compliance Tool erroneously separates out "processes, strategies and evidentiary standards" from "or other factors" used in applying the NQTL. Also, the Self-Compliance Tool requires the identification of "the sources" used to define the factors and an (evidentiary) "threshold" for each factor. To be clear, MHPAEA and its related regulations do not define the terms "processes, strategies, evidentiary standards, or other factors." It is unsupportable under the law to define these terms through the Self-Compliance Tool as opposed to the Tri-Departments initiating a requisite rulemaking proceeding.

Utilization Management

In general, many plans like Beacon use panels of medical experts to assess whether a particular utilization management protocol (such as prior authorization) should be applied to a particular service; these decisions are not based simply on one or two individual studies. As such, we recommend that the following example from the MHPAEA final regulations govern NQTL analyses:

A plan complies with parity rules in determining the NQTL of medical appropriateness for both MH/SUD and medical/surgical treatments "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." 45 C.F.R. 146.136(c)(4)(iii) Example 4.

Beacon notes 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; while physical health has biomarkers to indicate a disease or condition, behavioral health diagnoses are not as clearly identified. One way to ensure the provision of excellent care is to focus on the above example and reliance on panels of experts to make clinical determinations. Such an approach is more reliable than an overly rigid or imprecise benefit/service crosswalk approach.

Diagnostic Related Groups (DRGs)

While Diagnostic Related Group (DRG) reimbursement methodologies exist on the medical/surgical side and serve to act as a treatment limitation for inpatient stays, DRGs do not exist as frequently for MH/SUD treatments. In such situations, the Tri-Departments should deem that a plan's concurrent management is clinically appropriate and permissible for psychiatric hospitalizations, as long as general medical hospitalizations that are not reimbursed based on DRGs are also subject to concurrent review. Beacon remains committed to offering innovative value-based payment arrangements as well as DRGs, but thus far, many providers and facilities remain resistant to such efforts.

Reimbursement

For reimbursement rates, Beacon suggests that FAQ 7 should explicitly recognize that parity in process does not necessarily result in equal dollar amounts for medical/surgical and MH/SUD providers. To provide balance, the FAQ should be revised to show how factors used in determining provider reimbursement, when applied in a manner that is comparable to and no more stringent for MH/SUD as for medical/surgical benefits, can result in different dollar amounts that are permissible under MHPAEA.

Moreover, MH/SUD and medical/surgical providers are generally subject to an identical process for setting in-network, contracted rates. The parties begin at the base rate, and via arms-length negotiations reach the final rate, meaning that market forces, and not the chosen base rate, determine whether providers receive higher rates. Providers are not required to join a plan's network, and do so only after a voluntary negotiation has been concluded. In general, the processes and standards used to negotiate medical/surgical and MH/SUD rates are comparable, and applied no more stringently for MH/SUD benefits, in that they rely on free-market negotiations to arrive at the final result.¹

Beacon therefore recommends that Question 7 be revised to reinforce that the process, factors, and standards for determining provider reimbursement rates must be comparable, but the outcomes, or dollar amounts, may differ and still be compliant with MHPAEA.

Analysis of Medical Services for Behavioral Health Conditions

Beacon, as an exclusive behavioral health payer, has encountered much confusion among stakeholders and regulators regarding whether MHPAEA applies to a medical/surgical benefit for a behavioral health condition. The issues arise over a very specific set of circumstances, including speech and occupational therapy for Autism Spectrum Disorder, surgery for gender dysphoria, or nutritional counseling for eating disorders. Many of our clients have expressed concern that if speech therapy for Autism Spectrum Disorder is subject to MHPAEA and is unlimited in benefit, but speech therapy for a stroke is not subject to MHPAEA and may have a limited benefit, the resultant disparity may be viewed as

¹ If Congress had intended for MHPAEA to regulate private contractual arrangements, it would have said so. The Senate Committee Report indicates that MHPAEA was not meant to limit benefit management — S. 558 does not prohibit group health plans from negotiating separate reimbursement or provider payment rates and service delivery systems, or managing the provision of mental benefits in order to provide medically necessary treatments under the plan (Sen. Rep. No. 110-53, 110th Cong., 1st Session (2007) at p. 3).

discriminatory (not to mention confusing and hard to administer). Indeed, draft FAQ 10 leaves the impression that the underlying condition (medical/surgical or MH/SUD) of a given patient may require a different application of MHPAEA under the same plan for the same benefit. For example, using the scenario in the proposed FAQ 10, a patient receiving emergency room treatment for a laceration due to a car accident would not be considered subject to MHPAEA's protections, but if that same patient came in with a laceration resulting from a psychotic episode, MHPAEA would apply.

To resolve any confusion, we recommend that plans be allowed to use a reasonable method for defining such services as medical/surgical or MH/SUD benefits. For example, that method could define the service based on whether the service is most commonly or frequently used for a medical/surgical or MH/SUD condition, using the plan's annual claims experience to determine spend on the service in question. (Note: A plan may be able to define other reasonable methods.) We note that CMS previously addressed this issue – of defining benefits in the case of a treatment or service that is used to treat both medical/surgical and MH/SUD conditions – in an FAQ issued in October 2017 regarding MHPAEA compliance for Medicaid and CHIP programs and plans.² We believe that guidance is instructive for all scenarios where a plan must assign a treatment/service to one category of benefits or the other for purposes of plan design and administration of plan terms and conditions, including financial requirements, QTLs and NQTLs.

For example, if the member's plan uses annual claims experience for physical therapy services and finds that 87% of claims for physical therapy have a medical/surgical diagnosis and 13% have a MH/SUD diagnosis, the plan may then define physical therapy as a medical benefit for purpose of defining the applicable quantitative limits (e.g., annual visit limit) and financial requirements (e.g., copayment). If, however, the plan's claim experience showed that 48% of claims for physical therapy were for a medical/surgical diagnosis and 52% were for a MH/SUD diagnosis, the plan would have to treat physical therapy as a mental health benefit.

Template Disclosure Form

Beacon has concerns that the draft MHPAEA model disclosure request form requires significantly more information than previously understood to justify application of an NQTL. Beacon recommends that the Tri-Departments revise the model form to provide plans with the level of information that should be disclosed to consumers, including examples of sample disclosures. Such a model form could simplify the process for responding to an information request for determining whether a utilization management requirement is an allowable NQTL under MHPAEA.

² See <https://www.medicaid.gov/federal-policy-guidance/downloads/faq101117.pdf> ("A variety of LTSS benefits, such as personal care and respite care, could be defined as either MH/SUD or medical/surgical (M/S), depending on the condition of the beneficiary being treated. For these benefits, the state may define the benefit as MH/SUD or M/S for the entire beneficiary population using a reasonable method, such as whether the service is most commonly or frequently provided due to a MH/SUD or M/S condition. For example, if more than 50% of spending on personal care is for beneficiaries who are receiving the service due to M/S conditions, the state may reasonably define personal care services as a M/S benefit for the purposes of the parity analysis.)

To demonstrate the complexity of information required under the current draft model disclosure form, ECT provides an illustrative example. In a hypothetical, a plan decides that preauthorization for ECT is warranted after conducting the requisite NQTL analysis. The plan documents that 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 – electromyogram); 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. The plan also documents that ECT does not always produce the desired outcome of symptom reduction. Safety concerns exist.³ Accordingly, the plan uses medical management reviews to 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 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.

Despite the appropriate NQTL analysis above, the model disclosure form would still require a plan to disclose large quantities of technical information to support its ECT analysis, such as comparative effectiveness studies, clinical trials, professional protocols, published research studies, and thresholds for evidentiary standards. 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 utilization management practices, were developed prior to adoption of the MHPAEA. The model form 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 model form as written 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 simple and readable format, would better serve consumers in their quest to ensure that MH/SUD benefit utilization management practices are not discriminatory. The form seems to imply that there is no limit to the size and scope of information requests to which plans and issuers must respond because the form allows for enrollees to request information not associated with a particular treatment or condition.

³ See <https://www.federalregister.gov/articles/2015/12/29/2015-32592/neurological-devices-reclassification-of-electroconvulsive-therapy-devices-intended-for-use-in>. A draft rule 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 3,417 comments on its draft rule before the public comment period closed in late March.



As such, per the earlier recommendation, Beacon recommends that the Tri-Departments redraft the disclosure form, perhaps with a focus on the level and type of user-friendly information plans should disclose instead. If the model form remains unchanged, Beacon requests that the effective date for voluntary use of the model disclosure form would be January 1, 2019.

Conclusion

Beacon thanks the Tri-Departments for this opportunity to provide our comments on the MHPAEA guidance. 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 daniel.risku@beaconhealthoptions.com or 617.747.1255.

Sincerely,

A handwritten signature in blue ink, appearing to read 'Daniel M. Risku', is written over a blue horizontal line.

Daniel M. Risku
Executive Vice President & General Counsel
Beacon Health Options