



August 28, 2017

Submitted electronically via e-ohpsca-mhpaea-disclosure@dol.gov

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200 Constitution Ave., NW
Washington, D.C. 20710

Department of Health and Human Services
The Hubert H. Humphrey Building
200 Independence Ave., SW
Washington, D.C. 20201

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

Re: FAQs About Mental Health and Substance Use Disorder Parity Implementation and the 21st Century Cures Act Part 38

To Whom It May Concern:

The Pharmaceutical Care Management Association (PCMA) appreciates the opportunity to respond to the Frequently Asked Questions About Mental Health and Substance Use Disorder Parity Implementation and the 21st Century Cures Act Part 38 (hereinafter, FAQs) issued on June 16, 2017. In the FAQs, the Departments of Labor (DOL), Health and Human Services (HHS), and the Treasury (collectively, the Departments) issue a “compliance program guidance document” to discuss “disclosures” and the “availability of [employee welfare benefit plan information]” to consumers about mental health/substance use disorder (MH/SUD) benefits. The FAQs’ request for comments also raise questions around the Mental Health Parity and Addiction Equity Act (MHPAEA) disclosure process with respect to non-quantitative treatment limits (NQTLs), parity’s application to eating disorders, and a draft model disclosure form.

PCMA is the national association representing America’s pharmacy benefit managers (PBMs), which administer prescription drug plans and operate specialty pharmacies for more than 266 million Americans with health coverage through *Fortune* 500 companies, health insurers, labor unions, Medicare, Medicaid, the Federal Employees Health Benefits Program, and the Health Insurance Marketplaces established by the Affordable Care Act (ACA).

We recommend that the model forms or any other guidance related to this request be subject to formal rulemaking and not issued through FAQs. Should the Departments elect to proceed with guidance regarding a model disclosure, then we offer the following comments.

In line with the objectives outlined in the recent request for information (RFI) on reducing the regulatory burdens of the ACA,¹ PCMA believes a more user-friendly disclosure form, presented in an easily readable format would eliminate unnecessary burden and better serve enrollees in

¹ Request for Information on Reducing the Regulatory Burdens of the Patient Protection and Affordable Care Act issued in the Federal Register on June 12, 2017 (82 FR 26885).



understanding whether their health plan's MH/SUD benefits' utilization management (UM) practices are on par with those used for medical and surgical benefits.

PBMs work diligently to ensure compliance with parity requirements, involving clinical and administrative personnel to promote understanding and implementation of parity rules. The Departments have issued FAQ guidance pertaining to disclosure obligations under the MHPAEA for medical necessity determinations with respect to MH/SUD benefits. PBMs have been meeting those obligations under the MHPAEA standard for the past several years and will continue to assure they provide the necessary disclosures to consumers and clinicians when there are requests or appeals. Beyond parity, our members have been leaders in pioneering innovative programs focused on ensuring consumers have affordable access to quality, evidence-based pharmacy benefits through the use of UM, case management and care coordination tools that promote clinically sound, cost-effective prescription drug use and positive therapeutic outcomes.

1. Comments Specific to FAQ Part 34

In the FAQs, the Departments resolicit comments on questions previously raised in the ACA Implementation FAQs Part 34. Our responses are set forth below.

- a) Whether issuance of model forms that could be used by participants and their representatives to request information with respect to various NQTLs would be helpful and, if so, what content the model forms should include. For example, is there a specific list of documents, relating to specific NQTLs, that a participant or his or her representative should request?**

A properly structured model disclosure request form should be enrollee-friendly, presented in simple, clear language, and provide enrollees with useful information. We believe that general information on the processes and tools plans use to make pharmacy benefit decisions, rather than a list of documents relating to specific NQTLs, would be most beneficial to consumers in understanding how coverage determinations are made.

A model disclosure request form that follows a "check list" approach would provide beneficiaries with valuable information on their disclosures. This approach could include boxes that reference factors used by both MH/SUD and medical/surgical in implementing utilization management such as high variability in adherence to practice guidelines, high utilization relative to benchmark, variability in cost and service, and a high degree of provider discretion in type and length of treatment.

In designing a model disclosure request form, the key is to provide consumers with useful information as opposed to complex studies from medical journals. We question the benefit of providing documentation of all of the specific underlying processes, strategies, evidentiary standards, and other factors considered by the plan (including factors that were relied upon) in



determining that the NQTL will apply to a particular MH/SUD benefit. Enrollees do not typically request this information and these extraneous documents have the potential to place a large burden on health plans which in turn may result in additional administrative costs. We believe that a more user-friendly analysis in an easily readable format would better serve consumers in understanding whether MH/SUD benefits' UM practices are on par with those used for medical/surgical benefits.

Rather than overwhelming enrollees with significant amounts of documentation, we recommend keeping the disclosure requirements at a level where consumers will understand the material they receive. This can be done by providing general information on the processes and tools plans use to make pharmacy benefit decisions, rather than a list of documents relating to specific NQTLs. We believe this would be most helpful to consumers in understanding how coverage determinations are made. PBMs also utilize multiple avenues of communication with consumers, such as secure, online portals and toll-free call center numbers that consumers can use when communicating about coverage determinations, benefit design generally, and other concerns regarding their pharmacy benefits. Such portals and call centers represent examples whereby health plans and PBMs are already complying with MHPAEA disclosure requirements and other federal and state disclosure requirements. It is important to recognize the existing communication framework and that no one template will be appropriate in all circumstances. It is critical PBMs continue to be allowed the freedom to craft helpful, legally-compliant disclosure responses and not be bound to respond to a "one size fits all" disclosure request template in all instances.

We also recommend simplifying language in the "background" section to include only a brief and general description of the disclosure form, along with the instructions written between a 4th and 6th grade reading level as required by most state Medicaid programs.

- b) Do different types of NQTLs require different model forms? For example, should there be separate model forms for specific information about medical necessity criteria, fail-first policies, formulary design, or the plan's method for determining usual, customary, or reasonable charges? [Question for members: what should PCMA say about these forms in particular?] Should there be a separate model form for plan participants and other individuals to request the plan's analysis of its MHPAEA compliance?**

PCMA does not recommend separate model forms for requesting information on each type of NQTL, nor should there be a separate model form to request the plan's analysis of its MHPAEA compliance. We strongly believe using specific NQTLs as the basis for requesting disclosures risks the unintended consequence of adding confusion due to a proliferation of additional disclosures, undermining the Administration's goals of: reducing regulatory burden, provide stakeholders with clear guidance regarding the disclosures already required under current law, and providing enrollees with greater efficiency in the marketplace. Although a single model disclosure form may be useful and applicable in many instances, no one model form may be



appropriate in all circumstances. As such, we appreciate that the Departments continue to allow health plans the flexibility to develop their own legally-compliant disclosure forms.

- c) Whether issuance of model forms that could be used by States as part of their review would be helpful and, if so, what content should the model form include? For example, what specific content should the form include to assist the States in determining compliance with the NQTL standards? Should the form focus on specific classifications or categories of services? Should the form request information on particular NQTLs?**

We recommend that the model form not focus on specific classifications or categories of services, but rather than on the processes and tools used by plans. For example, the form could seek an attestation when the evidentiary standards used for determining whether a treatment is medically appropriate were based on scientific evidence published in peer-reviewed literature, professional society guidelines, or recommendations made by panels of experts with appropriate training and experience in the fields of medicine involved.

- d) What other steps can the Departments take to improve the scope and quality of disclosures or simplify or otherwise improve processes for requesting disclosures under existing law in connection with MH/SUD benefits?**

PCMA recommends that the content of the form go through the regulatory notice and comment period process to allow for sufficient public input and ensure that the model form does not create any new disclosure requirements or conflict with or confuse existing disclosure requirements.

- e) Are there specific steps that could be taken to improve State market conduct examinations and/or Federal oversight of compliance by plans and issuers?**

We encourage federal regulators to provide guidance for states that review parity compliance, including more information and expanded awareness of federal jurisdiction and state roles as another way of achieving consistent interpretation across oversight agencies, more regulatory certainty, less variation in interpretations, and greater consumer understanding of which federal and/or state laws apply to their individual circumstances.

2. Comments Specific to the Draft Model Disclosure Request Form

We have several recommendations for the Departments' consideration that we believe would make the model form more helpful to consumers in line with the Departments' goals. However, as currently drafted, we do not believe the model form will be very useful to consumers and will lead to a significant amount of unnecessary documentation.

- **Page 3-4.** Under Claim/Denial Information Request (check all that apply), the eighth sub-bullet regarding calculation of payment for out-of-network services does not seem to be consistent with the other NQTLs and appears to be directed more at providers rather than consumers. If that is the case, we recommend that this sub-bullet be deleted. If not, we request clarification.
- **Page 3.** The section allowing the form to be completed by an authorized representative does not indicate that the plan will need additional documentation on this status prior to sharing information with the named individual. Prior to disclosing any kind of information, health plans need to verify the identity and authority of all individuals making the request on behalf of the enrollee. If the identity or authority of such individuals is not known, health plans should clearly be permitted to deny such requests.
- **Page 4.** Under the next section regarding information being requested: We recommend that the Departments delete items #2-4. Beneficiaries seldom request this information and providing this level of detail will overwhelm beneficiaries with complex information pertaining to all facets of parity compliance regardless of its applicability to a participant's requested service. This irrelevant information has the potential place a large burden on plans without improving impact on the quality of service. Should the Departments retain these items, then we offer the following recommendations:
 - Include checkboxes enabling beneficiaries to request only the items they need.
 - The reading level of this form is much too high for the average consumer. In addition, if the regulators suggest the use of this form for Medicaid, most states have a required reading level of between 4th and 6th grade.
 - **Item #2.** We recommend that the factors used in the development of the limitation and the evidentiary standards used to evaluate the factors include a checklist listing such factors as: high variability in adherence to practice guidelines, high utilization relative to benchmark; variability in cost and service; and high degree of provider discretion in type and length of treatment absent conforming medical evidence. Similarly, the evidentiary standards used to evaluate the factors could include sources such as: scientific evidence published in peer-reviewed literature; professional society guidelines; recommendations made by panels of experts with appropriate training and experience in the fields of medicine involved; etc.

- **Item # 3.** The meaning under this section is unclear and should either be clarified or deleted as previously noted.
- **Item #4.** We suggest that providing the specific plan language in item #1 and identifying the medical/surgical and MH/SUD benefits to which it applies be sufficient. Moreover, it is important to emphasize that “parity” in the context of NQTLs does not mean that the results of application of such limits are the same across all benefits. Rather, the salient issue is whether clinically accepted, evidentiary standards are being applied in the same manner to medical/surgical, mental health, and substance use disorder benefits.

3. Additional Issues

The interim final rule Under the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (IFR) recognized that there are times when a direct comparison between physical health and MH/SUD does not make clinical sense and is not appropriate for beneficiaries. As such, the IFR included an exception to the requirement permitting the application of “more stringent” NQTLs with respect to mental health or substance use disorder benefits, “to the extent that recognized clinically appropriate standards of care may permit a difference.”² However, this exception was deleted from the Final Rule based on the Departments’ claim that the exception was not needed.³ We encourage the Departments to recognize that differences may exist between behavioral health and physical health in order to ensure that the best quality, evidence based care is being provided.

PCMA appreciates the opportunity to comment on the FAQs. We would be happy to respond to any questions you may have. Please feel free to contact me at (202) 756-5731 or wkrasner@pcmanet.org, or Mona Mahmoud at (202) 756-5738 or mmahmoud@pcmanet.org.

Sincerely,

A handwritten signature in cursive script that reads "Wendy Krasner".

Wendy Krasner
Vice President, Regulatory Affairs

² 75 FR 5410

³ 78 FR 68245