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May 3, 2010

Hilda L. Solis
Secretary
Department of Labor
200 Constitution Avenue, NW
Washington, DC 20210

Kathleen Sebelius
Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Timothy Geithner
Secretary
Department of the Treasury
1500 Pennsylvania Avenue, NW
Washington, DC 20220

Re: Interim Final Rules Under the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008; Final Rule; Docket No. CMS-4140-IFC; [RIN 0938-AP65]; 75 Federal Register 5410 (February 2, 2010).

Dear Secretaries Solis, Sebelius, and Geithner:

The American Psychiatric Association (APA), the national medical specialty society representing more than 37,000 psychiatric physicians, appreciates the opportunity to submit these comments on the Departments of Labor, Health and Human Services, and the Treasury (The Departments) interim final rule (IFR) on the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (Sections 511 and 512 of PL 110-343, October 3, 2008) (MHPAEA).[1] APA has also joined with the Parity Implementation Coalition in filing comments on the IFR, but we are pleased to offer our specific comments here.

It was estimated that enactment of MHPAEA would improve coverage for over 113 million people, including 82 million individuals covered by employer

[1] Pub. L. 110-343

sponsored plans that were not subject to state regulations. The law will ensure that mental health coverage will now be treated the same as all other forms of healthcare coverage and we greatly appreciate that the Departments have issued these rules on an interim final basis to ease implementation of the law. APA was pleased to submit comments on the Departments' request for information (RFI) which was issued on April 28, 2009, and to address the numerous areas of open interpretation in the statutory language. APA believes that issuing these rules on the interim basis is the best way to provide clear and consistent guidance to plans and issuers on how to structure their benefits to comply with MHPAEA and we look forward to working with the Departments in ensuring that compliance is met.

Classification of Benefits and Scope of Services

APA is extremely pleased that the Departments have taken the approach to classify benefits into specific categories and apply the requirements from MHPAEA across those categories. We believe that this is a logical system and will greatly simplify comparisons when determining if a plan or issuer has complied with the law.

We agree with the Departments that the appropriate determining criteria for finding the predominant financial requirements and treatment limitations should be within a given classification of benefits. We believe that it is required under the statute that the regulations from MHPAEA apply both *across* and *within* these classifications. APA also agrees with the Departments that six classifications of benefits proposed in the rule[2] are clear and will cover the full scope of benefits provided in both mental health and medical/surgical care. The IFR also states that a plan must offer benefits for any mental health or substance use disorder covered in each classification for which they also offer medical surgical coverage.

While the Departments do state that the definition of each classification may vary by plan, APA requests the Departments to clarify in the final rule or in any subsequent guidance that these classifications must cover all benefits provided by the plan. The Departments must clearly state that a plan may not exclude a particular service or benefit simply because it does not fall squarely into one of the six classifications proposed or because there is no analog on the medical/surgical side. There are frequently used mental health and substance use disorder (MH/SUD) services which do not fit neatly into one category or have a comparable medical/surgical service, but which nonetheless should be covered under MHPAEA. Additionally, APA would appreciate a clarification that insurers cannot create new benefit classifications for either mental health/substance use disorder treatment or medical/surgical care to skirt enforcement of the law as we have grave concerns that plans will create such classifications and shift definitions of certain benefits to avoid providing mental health and substance use disorder benefits at parity.[3]

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[2] The six classifications as described in the rule are: inpatient, in-network; in-patient, out-of-network; outpatient, in-network; outpatient, out-of-network; emergency services and prescription drug benefits.

[3] For a full discussion of the scope of comparable and non-comparable services and types of treatments, we refer the Departments to the comments submitted by the PIC on April 30, 2010.

APA urges the Departments to revise this section for the final rule and make it clear that plans may not circumvent the law or the rules by claiming that a benefit or service falls outside of these six classifications and therefore does not have to be covered.

Recommendations: APA supports the six benefit classification scheme as outlined by the Departments, however we urge the Departments to clarify that the universe of health benefits for these purposes is limited to these classifications. We also urge the Departments to clarify that these classifications address the issue of scope of services for this reason.

Cumulative Financial Requirements and Quantitative Treatment Limitations

APA generally agrees with the approach that the Departments have taken with regard to determining the "predominant limitation" applied to "substantially all" benefits in a plan. As we expressed in our comments to the RFI, APA believes that it would be consistent with prior policy to set limits in line with those set for the Mental Health Parity Act of 1996 (MHPA). We also support the Departments' policies regarding those benefits which are subject to "zero sum limits." We agree that services which are not subject to a copayment, such as well baby visits or visits for allergy shots, should not be included in the calculations when determining the predominant limit.

APA would like to express our strong support for the Departments' clarification that cumulative financial requirements, such as deductibles and out-of-pocket maximums, must be structured as a single combined limit. We stated in our RFI comments that we fully supported this position and believe that it is far more consistent with the intent of MHPAEA. As stated in the statute, MHPAEA prohibits financial requirements including deductibles and out-of-pocket maximums which are more restrictive than applied to medical and surgical benefits and requires that there be no separate cost-sharing requirements applicable only with respect to mental health or substance use disorder treatment. APA believes that this language demonstrates the intent of Congress to discourage, if not outright prohibit, the application of separate cumulative financial requirements.

APA believes that this position will greatly benefit patients who seek treatment for mental health and substance use disorder treatment. In particular, this protection would most directly benefit those with serious and persistent mental illness, many of whom have co-morbid medical and surgical conditions and would have difficulties meeting two separate deductibles. Frequently, patients first seek treatment from a primary care physician or similar provider for the physical symptoms of a mental illness (e.g. fatigue, loss of appetite, etc.) before being referred for mental health care. Sometimes the treating physician will notice that an existing patient is presenting with signs of a mental illness and subsequently refer him or her for mental health evaluation and treatment. In these instances, the patient has frequently already met the deductible and the imposition of a separate, and equally high, out-of-pocket expenditure may serve as a deterrent to seeking appropriate care. In this setting, as in so many others, "separate but equal" is inherently not equal.

Some comments submitted to the Departments asserted that separate, but equal deductibles would actually be more beneficial to patients given the lower mental health deductibles provided by some plans. APA is unaware that such allegedly beneficial deductibles are standard practice. Further, there is nothing in MHPAEA that would prevent a plan from providing mental health and substance use disorder services at lower cost sharing of any kind, including setting a lower threshold within the deductible for MH/SUD services. Separate deductibles only serve as a barrier to accessing mental health treatment and would undermine the law. Therefore, APA strongly supports the interim final regulation as it requires plans to maintain single combined deductibles or out-of-pocket maximums for all benefits and urge the Departments to finalize this regulation.

Recommendation: APA strongly supports the requirement that plans offer a single combined deductible for all health costs as we believe it follows the intent of MHPAEA and will greatly benefit patients. We urge the Departments to include this requirement in the final rule.

Non-Quantitative Treatment Limitations

APA strongly supports the Departments' inclusion of non-quantitative treatment limitations (NQTLs) as impermissible restrictions under MHPAEA and we believe that this addresses the central intent of the statute. As we stated in our comments on the RFI, the most visible methods of controlling costs and perpetuating discrimination, such as visit limits and higher cost sharing, are not always the most insidious. NQTLs prevent patients from gaining access to adequate mental health and substance use disorder treatment, which is the very problem MHPAEA sought to rectify.

APA believes that the statute includes the authority for the regulations to cover these NQTLs and that the Departments acted appropriately by including them in the rule. The section concerning the parity of treatment limitations in MHPAEA closely follows the language concerning financial requirements, with some key differences. The statute states that the definition of treatment limitations "includes limits on the frequency of treatment, number of visits, days of coverage, or other similar limits on the scope of duration and treatment."[4] However, the language regarding financial requirements has examples yet no similar reference to "other similar limits." We believe that these NQTLs are exactly the limits on scope and duration of treatment envisioned, yet not enumerated, by Congress in the statute.

Since MHPAEA became effective, we have seen a number of confusing and often deceptive practices on the part of insurers which we believe are intended to circumvent the law. Prior to the issuance of the IFR, there was a wide variation in how the law was applied and in many instances, these changes actually prevented patients from accessing care. APA was informed by many of our members that insurers began imposing new

[4] 29 U.S.C. § 1185a(a)(3)(B)(iii).

requirements for prior authorization and the submission of treatment plans for mental health services where there were no comparable requirements on the medical/surgical side. In other cases, we received examples of insurers dropping coverage for essential mental health services when there was ample coverage for similar benefits for medical/surgical care. While the stated reason for these requirements in most cases was benefit management, these policies went far beyond legitimate practice. Further, several insurers falsely stated that the imposition of these new requirements was in fact *required* by MHPAEA. Whether these policies were designed to limit access to appropriate mental health care, drive health professionals out of the insurers' networks, or simply to cut costs, APA firmly believes that these practices are a clear violation of MHPAEA as they limit patients' access to care and perpetuate the very discriminatory practices that MHPAEA was enacted to eliminate.

Upon receiving reports of this shift in the absence of federal guidance, APA moved swiftly to intervene to pressure insurers to reverse these changes and alerted the Departments to these attempts to undermine the law.[5] Given the clear reaction from the insurers to take advantage of any ambiguity in the statute and impose policies to undermine the effectiveness of the law, we are extremely pleased to see that the Departments addressed these practices in the regulations.

The application of NQTLs such as restrictive formulary management, overzealous application of prior authorization and the discriminatory methods of calculating usual and customary rates are all limits on the scope and duration of treatment that a patient receives. For example, if an insurer requires prior authorization before any visit to a psychiatrist and also requires that the psychiatrist submits and has a treatment plan approved after every three visits when no such requirements are applied comparably to the medical/surgical side, it is reasonable to conclude that the main purpose of such requirements is to discourage treatment by making it unreasonably difficult for a psychiatrist to treat a patient. Similarly, if the insurer has set reimbursement rates for psychiatrists so unreasonably low that it effectively forces those physicians out of the network, their patients will be unable to maintain the continuity of the relationship which is essential to good care. This is a clear non-quantitative limit on the scope and duration of the treatment the patient receives and which is almost never imposed on the medical/surgical benefit.

Additionally, many insurers use different provider network standards for MH/SUD coverage or use a different calculation to set UCR rates for mental health professionals. Not only do we believe that these practices are similarly prohibited NQTLs, we would like the Departments to clarify that these are two independent NQTLs and that meeting a network access standard does not relieve a plan from an obligation to use the same method of calculating reimbursement rates for MH/SUD services. APA is concerned that without a clear statement to this effect and examples demonstrating the issue, plans will inappropriately assume their duty to satisfy both will be discharged after complying with one in a superficial manner. However, this will result in the same access issues for patients as existed before the enactment of MHPAEA.

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[5] See APA's letter to the Departments dated November 2, 2009, as attached to these comments.

APA appreciates that the Departments addressed many of the issues raised in our comments on the RFI, in addition to those raised by many other groups, and that the regulations preserve the intent of the law to abolish discriminatory insurance practices so frequently applied to mental health and substance use disorder benefits. While many of the comments submitted on the RFI focused on current industry practices and how to maintain those management techniques, passage of MHPAEA was a clear statement that the status quo is no longer acceptable and these interim regulations support that statement. Therefore, we fully support the inclusion of NQTLs in the IFR and urge the Departments also add additional illustrations and examples of NQTLs including:

- Prior authorization and concurrent review requirements for outpatient services, in and out-of-network;
- Prior authorization and concurrent review requirements for inpatient services, in and out-of-network;
- Reimbursement rate issues for in and out-of-network;
- Formulary design;
- Service coding;
- Provider network criteria;
- Policy coverage conditions and exclusions; and
- Geographic limitations to state of issuer, in and out-of-network.

We understand the difficulties that the Departments faced when deciding on an operative standard by which to judge whether the NQTLs were more restrictive in a MH/SUD benefit as compared to a medical surgical benefit. We concur with the Departments that the NQTL on the MH/SUD benefit should be comparable to the limit on the medical/surgical benefit and the limit on the MH/SUD benefit should not be applied more stringently than on the medical/surgical benefit. We believe that this standard follows the intent and the language of the MHPAEA statute. We do, however, have some concerns and request that the Department clarify several points in the final rule.

APA fully agrees with the Departments that MHPAEA prohibits the imposition of NQTLs through "[...]any processes, strategies, evidentiary standards, or other factors used in applying the non-quantitative treatment limitation to mental health or substance use disorder benefits in the classification are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in applying the limitation with respect to medical/surgical benefits in the classification, except to the extent that recognized clinically appropriate standards of care may permit a difference."[6] We believe that this is a reasonable standard. We also concur with the examples provided in which plans apply similar limitations in disparate methods or use counseling services as a gatekeeper on the MH/SUD side as violating the law.

We have serious concerns that the exception noted in the IFR may inadvertently undermine the strength of the regulations. For example, the use of the term "recognized

[6] 75 Fed. Reg. at 5416.

clinically appropriate standards of care" which may permit a difference in application may allow insurers to use proprietary standards of treatment which are lower than the norm. We request that in the final rule, the Departments clarify that any "recognized" standard of care for purposes of the NQTL exceptions process must be: (1) an independent standard that is not developed solely by a single health plan or plans; (2) based on input from multiple stakeholders and experts, such as academic researchers, senior practicing clinicians, and consumer and advocacy leaders with subject matter expertise in addition to a health plan or its advisory panels; (3) recognized or accepted by multiple nationally recognized physician and patient organizations and/or nationally recognized accrediting organizations that are responsible for developing quality standards; and (4) based on objective scientific evidence, such as peer-reviewed publications of control group research trials or expert consensus panels. We believe that there is ample evidence to support this practice give CMS's reliance on similar input for Medicare national coverage determinations and through the work of the Medicare Coverage Advisory Committee (MEDCAC). This will prevent the application of arbitrary exclusions simply to circumvent the regulations as written and therefore we urge the Departments to clearly define "recognized clinically appropriate standards of care" in the final rule or any further guidance.

While we agree with the "comparable" and "no more stringently applied" standard for NQTLs, we are concerned that there is not a clear statement that these limitations must also comport with the aforementioned "predominant" and "substantially all" test for all limitations under the law. The statutory test for all limitations applied to a MH/SUD benefit under the law is that they must not be more restrictive than the predominant limitation applied to substantially all the medical/surgical benefits. Therefore, it must be made clear that the NQTLs must also meet that requirement. It would be inappropriate if the regulations allowed certain NQTLs to be applied to MH and SUD treatment when they only apply to a fraction of the medical/surgical benefits. APA urges the Departments to clarify this section of the regulation in the final version of the rule.

Recommendations: APA believes that regulation of NQTLs is a critically important issue under MHPAEA and that the law requires that they be regulated in the same manner as quantitative treatment limitations. Therefore, we recommend the Departments finalize the requirements imposed on NQTLs in this IFR and also clarify that they are subject to the same "predominant" and "substantially all" standards as QTLs. We also urge the Departments to add to the list of NQTLs which are covered under MHPAEA.

Availability of Plan Information

MHPAEA includes a requirement that plans must disclose the reason for any denial of reimbursement or payment for services with respect to MH/SUD benefits, if requested. However, patients have encountered significant delays in receiving the required disclosure when requested and APA requests that the Departments set forth a timetable for plans to provide such information. This is particularly important when the denial is based on medical necessity criteria since, absent any explanation from the plan, the

patient has little to no information as to why payment was denied and cannot seek to remedy the situation. Most patients will try to appeal the decision and the summary plan information about medical necessity determinations is inadequate for this purpose. Therefore, it is essential that the provision of this information be timely. Specifically, APA urges the Departments to require that information regarding the plan's medical necessity criteria be provided to the insured within three days of an adverse care decision

Recommendation: APA urges the Departments to require that, in the event of a denial, plans provide patients information regarding medical necessity criteria within three days to facilitate patient appeals.

Application to Medicaid Managed Care Plans

APA has significant concerns that the Departments have omitted an essential part of the regulations under MHPAEA, namely the application of these regulations to Medicaid managed care plans. The statutory language of MHPAEA clearly applies to Medicaid plans and therefore Medicaid managed plans must comply with the law. The Departments, however, have exempted these plans from the regulations without a clear reason. Given the high percentage of Medicaid beneficiaries whose benefits are administered through a managed care program and the high number of Medicaid beneficiaries with mental illness, APA believes the lack of regulation in this area could be confusing at best and also potentially harmful to patients. We urge the Departments to move swiftly to issue regulations for this segment of the population and recommend that these regulations and guidance be consistent with those issued under MHPAEA.

MHPAEA modified the Public Health Service Act (PHSA) to require that group health plans comply with the same policies as all other plans covered by the law and the Medicaid managed care statute refers to this section and mandates that managed care plans "comply" with its provisions. Specifically, the Social Security Act Section 1932(b)(8) specifies that "[e]ach Medicaid managed care organization shall comply with the requirements of subpart 2 of Part A of title XXVII of the PHSA [42 U.S.C.A. 300gg-5 *et seq.*] insofar as such requirements apply and are effective with respect to a health insurance issuer that offers group health insurance coverage."[7] The statutory reference in the quote refers to the mental health parity provisions as passed in the Mental Health Parity Act (MHPA) of 1996 and as modified by MHPAEA. Thus, the Medicaid managed care statute requires that these plans comply with both the 1996 and the 2008 parity requirements.

Given the clear application of the law to these types of plans and the potentially significant impact of the lack of guidance for these plans, it is imperative that the Departments offer regulatory guidance on this issue for Medicaid managed plans. APA also asks that this guidance be consistent with, if not the same, as the regulations and guidance issued for all other plans covered by MHPAEA to avoid any confusion in application.

[7] 42 U.S.C. § 1396u-2(b)(8) (2000).

Recommendation: It is essential for the Departments to ensure comprehensive and uniform compliance with MHPAEA and therefore we urge the Departments to swiftly issue regulations for Medicaid managed care plans and that these regulations be substantially similar, if not the same as the IFR.

Preemption and State Laws

As APA noted in our comments to the Departments on the RFI, numerous states had already implemented their own mental health parity laws at the time that MHPAEA was enacted. While these laws vary greatly from state to state, many of them were a response to the weaknesses in MHPA of 1996 and contained parity protections similar to those in MHPAEA. As stated in our earlier comments, APA believes that state parity laws with stronger protections than those contained in the MHPAEA will not ordinarily be preempted by the Act and strongly supports the Departments' statement in the IFR that confirms that interpretation.

Recommendation: APA agrees with the Departments that MHPAEA should not supersede the application of stronger state laws on parity and urge the Departments to include this guidance in the final rules.

Cost Exemption

MHPAEA permits an exception to the mental health parity requirements for plans that experience a cost increase of two percent in the first year of implementation of parity and one percent in subsequent years.[8] As APA indicated in our comments on the RFI, it is unlikely that many insurers will apply for the cost exemption since past experiences with parity implementation, at both a federal and state level, show that costs do not increase dramatically. However, we appreciate the Departments inviting comments in order to provide additional guidance in this area.

The statutory language of MHPAEA is clear that this exemption must be based on actual costs incurred, as was the case with the implementation of the cost exemption provisions of MHPA of 1996. It would be a clear violation of the law to allow any cost projections or determinations of cost increases based on actuarial estimates. Therefore, the Departments should reject any argument to allow plans to use actuarial cost projections to establish an exception to MHPAEA.

In implementing MHPA of 1996, the Departments similarly implemented an exception to parity requirements for plans whose costs increased one percent. The regulations discussed at length the method for calculating the cost increase. The 1996 regulations outline various options for making the calculation, including a purely retrospective approach where increased costs are based on actual experience, and a purely prospective approach where increased costs are based on actuarial projections. The Departments adopted a modified retrospective approach based on actual costs over a certain period of

[8] 29 U.S.C. § 1185a(c)(2)(A).

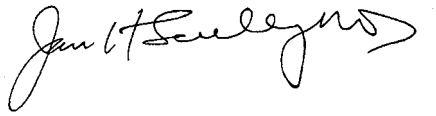
time. The Departments believed that using the costs that the plans actually incurred was important to assure that exceptions were "based on actual experience under the MHPA's parity requirements and not on projections or estimates of such experience." In like manner here, the Departments should ensure that actual costs, and not actuarial projections are used to determine eligibility for the exemption.

The 1996 regulations also set out a specific formula for calculating the one percent exception. The formula's numerator and denominator both relied on a calculation of "incurred expenditures."[9] As stated by the regulations, the term "incurred expenditures" means "actual claims incurred during the base period."[10] Once again, the Departments were clear that the exemption calculation must be based on actual costs. We request that the Department reject any argument to the contrary.

Recommendations: APA recommends that the Departments clarify in the final rule that any application for the cost exemption must be retrospective and based on actual costs incurred, as opposed to projected or estimated costs.

Thank you for your consideration of these comments on this interim final rule. We look forward to working with the Departments in the future to develop and implement any policy change. If you have any further questions, please contact Nicholas Meyers, Director, Department of Government Relations, at nmeyers@psych.org or Jennifer Tassler, Deputy Director, Regulatory Affairs, at jtassler@psych.org or at (703) 907-7800.

Sincerely,



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Medical Director and C.E.O., American Psychiatric Association

[9] 62 Fed. Reg. 66955.

[10] *Id.*

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November 2, 2009

The Honorable Hilda L. Solis
Secretary of the Department of Labor
200 Constitution Avenue, NW
Washington, DC 20210

The Honorable Kathleen Sebelius
Secretary of the Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

The Honorable Timothy Geithner
Secretary of the Department of the Treasury
1500 Pennsylvania Avenue, NW
Washington, DC 20220

Re: Implementation of the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008.

Dear Secretaries Solis, Sebelius, and Geithner:

I am writing to you on behalf of the American Psychiatric Association (APA), the medical specialty representing more than 38,000 psychiatric physicians nationwide, to alert the Departments of Labor, Health and Human Services, and Treasury to problems regarding the implementation of the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA) in the absence of federal regulations. I am also urging the Departments to issue guidance to insurers on how to properly comply with the law.

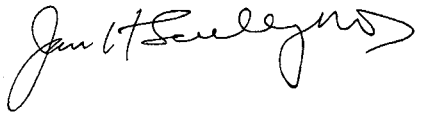
We understand from letters recently sent from Secretary Sebelius to Senator Al Franken and Representative Patrick Kennedy that the regulations implementing the MHPAEA will be delayed until January of 2010. However, APA has become aware that many health plans are imposing new requirements on mental health professionals under the guise of benefit management which seek to undermine the intent of the law. For example, many plans are now requiring prior authorization and treatment plans for mental health treatment where there are no comparable requirements imposed on medical and surgical treatments. Not only is this

in violation of the law against discriminatory treatment limitations, but also undermines the sufficiency of the network of mental health professionals as it drives providers out of health plan networks. APA believes that this practice is in blatant contradiction of the intent of the MHPAEA and is occurring due to the absence of federal guidance in this area. We are urging the Departments to take immediate action to stop this practice.

Further, APA has heard that some plans are taking an inappropriately limited view of the scope of services covered under the MHPAEA definition of benefits. While the law states that "benefits" means "benefits with respect to services," some plans are interpreting that to exclude coverage of essential treatment at all levels of care for mental illness and substance use disorder. We have spoken to insurers who assert that some services fall outside of the scope of benefits covered under MHPAEA, such as residential services for an inpatient benefit. APA believes that this position is not in line with the stated intent of the law and will prove to be dangerous for many patients who will not be able to afford complete treatment. This is particularly true with respect to coverage for alcohol and substance use disorder treatment and pediatric services which would be targeted through these policies. We recommend that the Departments take a close look at these insurance practices and clearly define the scope of services in the forthcoming regulations to avoid potential harm to a vulnerable population.

APA has been working with our members to gather information these changes that insurers are making and is prepared to offer examples of discriminatory practices. Thank you for your consideration of these comments and we look forward to working with the Departments of Labor, Health and Human Services, and Treasury on these important issues in the future. If you have any further questions, please contact Jennifer Tassler, JD, Deputy Director, Regulatory Affairs, at jtassler@psych.org or at (703) 907-7842.

Sincerely,



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