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HEALTH SERVICES

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July 25, 2011

Submitted via the Federal eRulemaking Portal **http://www.regulations.gov**

Office of Health Plan Standards and Compliance Assistance
Employee benefits Security Administration
Room N-5653
US Department of Labor
Attention: RIN 1210-AB45
200 Constitution Avenue NW
Washington DC 20210

Office of Consumer Information and Insurance Oversight
Department of Health and Human Services
Attention: CMS-9993-IFC2
P.O. Box 8010
Baltimore MD 21244-1850

U.S. Department of the Treasury
Internal Revenue Service
Attention: CC:PA:LPD:PR (REG-125592-10)
Room 5205
P.O. Box 7604
Ben Franklin Station
Washington DC 20044

Dear Sir or Madam:

Magellan Health Services (Magellan) welcomes the opportunity to comment on the Amendment to the Interim Final Rules for Group Health Plans and Health Insurance Issuers Relating to Internal Claims and Appeals and External Review Processes Under the Patient Protection and Affordable Care Act (Amended IFR). As one of the largest specialty health care management organizations in the country, Magellan is responsible for the administration of various specialty health benefits provided by our customers to their group and individual health plan members. Magellan's customers include both health plans and employers, covering millions of members nationwide. While we appreciate the positive changes that this amendment makes to the original IFR, there are still a few issues that we would like to see the Departments address in the future. These are detailed below.

Translation Requirements

We support the revisions to the translation requirements that remove the requirement to calculate threshold languages at the group level and to provide proactive 'tagging and tracking'. This level of complexity would have created unnecessary administrative complexity and cost. While we appreciate the relative simplicity of the revised provision, we would like you to consider further amendments to assist plans with compliance. For instance, insured plans operating in only one state or just a small number of states are now required under these provisions to assess whether any of their membership resides in out-of-state counties where a language threshold exists. When a plan identifies membership in a county with a language threshold, the plan will need to make provisions for translation services by contracting with a vendor and putting processes in place for translations, all potentially for one member or a small number of members who may never even utilize their health plan services. We would recommend that if a plan is an insured plan regulated by a state, then they should only be required to comply with translation requirements for counties within that regulating state.

Plans will also encounter some difficulty in determining when they have members who reside in a county that meets a language threshold because, as a general rule, county is not part of a mailing address. Plans will need to research county locations by zip code to convert zip code locations into county locations. In some instances zip codes break across counties in which case identifying the county will require even further research. We recommend that language thresholds be designed by zip code rather than by county so that plans can more readily identify when members are entitled to translations.

In addition, we would ask that you clarify the preamble reference on page 37214 which states that "For ease of administration, some plans and issuers may choose to use a one-sentence statement for all notices within an entire State (or for a particular service area) that reflects the threshold language or languages in any county within the State or service area. For example, statewide notices in California could include the relevant one-sentence statement in Spanish and Chinese because, using the data from Table 2, Spanish meets the 10 percent threshold in Los Angeles County and 22 other counties and Chinese meets the 10 percent threshold in San Francisco County. This would be a permissible approach to meeting the rule under this amendment." Does this mean that if the relevant statement were included in both languages statewide in California that the plan would therefore be obligated to provide translation services in those languages (both verbal and written) to any requestor within the state, or could such translations be limited only to members residing in the actual counties that meet the threshold requirements for those languages? Our concern relates primarily to the cost of providing written translations to all members within a state who request it regardless of location. Ideally we would like to be able to include all four languages on all letters to avoid missing a member who lives outside of the service area if the regulatory language remains as it does today, but we are reluctant to do so if it means that we will be obligated to provide written translations for all members who request translation regardless of whether or not they actually live in threshold counties. We have some customer health plans interpreting this regulation as requiring these translations to be provided to anyone who asks, simply by virtue of the statements being included on the correspondence.

We request that the regulations clarify the impact of translation requests on turnaround times for notices. In our experience, translation companies currently take five to seven business days to

return translation of a letter to a plan; the plan then needs at least one business day to forward a letter to the member. Given the likely greater demand for translation services created by the requirements in the IFR, it is likely that translation companies will require additional time to complete translations. We recommend that the regulations suspend applicable timeframes from the date a notice is sent to a translator until the date the plan receives the translated document, so long as the plan makes available an oral translation of the document within the prescribed timeframe.

You specifically requested comments on whether or not health insurance issuers should be required to provide language services in languages that do not meet the requisite threshold for applicable non-English language, if so requested by the administrator or sponsor of the group health plan to which the coverage relates. We strongly oppose any modification of the regulation that would make this a requirement. In order for insurers to be prepared to comply with such a request, they would need to have identified vendors to provide translation services and either executed contracts with these vendors or be prepared to do so upon short notice. However, because these requests would be for non-threshold languages, there would be no indication for the insurer as to what languages might be requested in order for them to identify a proper vendor and prepare to meet such a requirement. For some languages it is very difficult to find a qualified translation service. A requirement like this would be difficult to comply with and may result in insurers incurring administrative costs to prepare for requests that may never materialize. A plan sponsor could always request or contractually require an insurer to provide translation services in any languages of their choosing but making it a legal requirement for insurers to comply with all requests would not be prudent and would impose the costs of preparing for translation requests in non-threshold languages on plans that do not request such broader translations. This is a matter better left to negotiations between plans and their insurers.

Limited Scope of Claims for External Review and Binding Nature of the IRO Decision.

We strongly support the revision limiting the scope of claims which are eligible for external review strictly to cases that involve medical judgment, and we urge you to make this revised scope the permanent standard. External review should be restricted to medical decisions such as medical necessity and experimental treatment, and should also be limited to the issue or question presented in the appeal. We urge you to clarify that this was what was intended by 'medical judgment'. If a claim is denied for an administrative reason (e.g. failure to precertify in accordance with plan procedures) then that claim should not be eligible for external review. We believe there will be some confusion over what constitutes medical judgment without further clarification. In our experience with external review since January 2011, we have found that Independent Review Organizations (IROs) are somewhat frequently basing their decisions on matters far broader than the specific issue or question presented to them (for example, addressing the plan's choice of benefit design or contractual provisions rather than the medical necessity or appropriateness of the service/treatment at issue), and therefore changing the actual terms and conditions contained in the member's plan.

The following are some examples from our own experiences since putting the IRO process in place. These types of incorrect determinations have occurred despite our use of accredited IROs.

Examples

#1: In a plan that covers both in-network and out-of-network treatment, a member insisted on seeing a particular out-of-network provider and demanded payment at the in-network level. Because the plan had in-network providers who treat the particular diagnosis and those providers had appointments available, the plan denied payment at the in-network level and upheld the decision in internal appeals. The IRO overturned the denial on external review becuase the member was not satisfied with the plan's network providers. Under the plan, benefits are not available for any charges that the claims administrator indicates are not a covered health service. Although we determined that the charges were not covered health services, the IRO overturned our decision without reference to plan provisions.

This kind of determination made by the IRO severely undermines the plan's benefit design which is intended to give preferred benefits for care rendered by network providers. By allowing plan members to disregard network status in picking a provider and then forcing the plan to pay at the in-network level, the plan loses in at least three respects: (1) the plan ends up paying more for the service because the in-network level is applied to the provider's charges which are inevitably higher than negotiated contract rates charged by in-network providers; (2) the ability of members to obtain in-network payment from any provider regardless of network status creates a huge disincentive for providers to participate in a plan's contracted network; and (3) non-contracted providers have no commitment to cooperate with the plan's utilization management or quality improvement procedures, and may not meet the plan's strict quality of care requirements for providing care to the plan's members. We believe that these problems are inherent in allowing IROs to make judgments that out-of-network providers should be paid at an in-network reimbursement level. In making provider networks available to their members, plans have an obligation to assure network providers are qualified to provide services, but plans have no obligation to make available the top specialist on each idiosyncratic manifestation of each diagnosis. Giving IRO's unfettered discretion to allow members to avoid using network providers will undermine plan networks and drive up health care costs.

#2: The plan denied a claim for services which had already been rendered due to lack of preauthorization as required by the terms and conditions of the plan, and upheld the denial in internal appeals. The reviewer for the IRO misunderstood the denial to be a medical necessity decision in which preauthorization had been denied; he reviewed the case for medical necessity and found the care was medically necessary. By incorrectly transforming an administrative denial into a clinical denial, the IRO decision allowed a member to bypass the plan requirement to obtain preauthorization before care is rendered; continued decisions like this would nullify the prior authorization requirement in the plan design. Under the regulations, plans have no recourse for such incorrect and inappropriate IRO decisions.

#3: The plan was presented with insufficient clinical information to render a medical necessity determination on a proposed admission to an out-of-state residential treatment facility, and therefore offered to have the patient evaluated at a facility in the patient's home state in order to develop enough clinical information regarding medical necessity to render a benefit decision with respect to the need or appropriateness for treatment at the out-of-state facility. The offer was declined by the patient, and so prior authorization was denied due to insufficient information upon which a medical necessity decision could be made. Upon external review, the IRO determined that admission to the out-of-state residential treatment facility was medically necessary. The IRO also determined – beyond the scope of the questions for review - that the

member required 30 days of residential treatment, even though the member had never been clinically evaluated by anyone for the necessity or appropriateness of residential treatment at the time the external review decision was rendered. By determining 30 days to be medically necessary, the IRO decision arbitrarily and inappropriately revised the terms and conditions of the benefit plan, which included both prior authorization and, subsequently, concurrent review for continuing medical necessity for inpatient and residential treatment. Under the regulations, plans have no recourse for the IRO's unfettered modification of the benefit plan design.

We recommend that you consider the creation of an avenue to redress patently incorrect determinations made by the IROs, such that any arbitrary and capricious determinations by IROs should be subject to a review process. It would be extremely beneficial to have a process in place to determine if the IRO exceeded the scope of their authority in ruling on benefit design or contractual issues rather than medical necessity.

Mental Health Parity Benefit Design is not an Appropriate Example of a Claim Involving Medical Judgment for External Review

We take objection to one of the scenarios that you list on page 37216 as an example of a situation in which an adverse determination is considered a claim involving medical judgment. The last scenario is "Whether a plan is complying with the nonquantitative treatment limitation (NQTL) provisions of the Mental Health Parity and Addiction Equity Act (MHPAEA) and its implementing regulations, which generally require, among other things, parity in the application of medical management techniques." The nonquantitative treatment limitations, which is a term and concept that do not exist in the MHPAEA but were created by the implementing regulations, are defined by an illustrative listing which includes;

A. Medical management standards limiting or excluding benefits based on medical necessity or medical appropriateness, or based on whether the treatment is experimental or investigative;
B. Formulary design for prescription drugs;
C. Standards for provider admission to participate in a network, including reimbursement rates;
D. Plan methods for determining usual, customary, and reasonable charges;
E. Refusal to pay for higher-cost therapies until it can be shown that a lower-cost therapy is not effective (also known as fail first policies or step therapy protocols); and
F. Exclusions based on failure to complete a course of treatment.

The parity regulation states that "A group health plan may not impose a nonquantitative treatment limitation with respect to mental health or substance use disorder benefits in any classification unless, under the terms of the plan as written and in operation, any processes, strategies, evidentiary standards, or other factors used in applying the nonquantitative 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." 29CFR 2590.712 (c)(4)

As a behavioral health benefits management vendor to numerous health plans and employers across the country, when the parity regulations were released to discuss the NQTLs, we conducted detailed analyses over the course of several meetings with each of our customers, and, for our employer customers, with their medical management vendors. Each analysis involved an interdisciplinary team of clinicians, network managers, and legal counsel to ensure that the benefit design has comparable processes for medical/surgical benefits and the mental health and substance use disorder benefits. We also noted instances where there were clinically recognized standards of care that differed across the benefits and resulted in benefit differences supported by these industry wide standards of care. Based on these combined efforts, plans made plan design adjustments as needed to ensure compliance with the regulations in connection with NQTLs; for some customers, we implemented changes to ensure comparability with respect to their medical/surgical benefits.

The benefit design of a plan should not be able to be questioned or, even worse, undermined, in the context of an IRO review of a Plan adverse determination with respect to a particular treatment. We disagree that a determination on the application of the NQTLs involves medical judgment. It would be impossible for an IRO reviewing a single case to determine whether or not the process used to apply a NQTL to the plan's mental health benefits is comparable to, and no more stringent than, the process used to apply the same NQTL to the plan's medical/surgical benefits. It is inappropriate to suggest that an IRO, which is established to review individual cases using medical judgment, would be qualified to undertake and issue judgment upon a plan's benefit design, contractual provisions, or the processes, strategies, evidentiary standards, or other factors used in applying the terms and conditions of the plan. Medical judgments have very little, if anything, to do with the issues related to parity compliance. And, as described above, whether an NQTL meets the requirements of the parity regulations is generally not a simple matter that can be determined by simply looking at facial differences; it also takes an understanding of the methodologies and rationales for a plan's handling both medical/surgical benefits and behavioral health benefits. IROs are not equipped to engage in such examinations. Moreover, because of the additional time such examinations would take, entrusting IROs to engage in the type of analysis required to render a fair judgment on mental health parity would drastically increase the cost of such external reviews. In addition, a ruling by an IRO related solely to benefit design could cause a plan to have to re-work their entire benefit design mid-plan year which would be quite disruptive to other members and would have the potential to significantly impact plan costs as well. We urge you to retract this as an example of a medical judgment issue eligible for IRO review.

Model Notices and Letter Requirements

We appreciate the Departments issuing model notices for health plans, and see the potential value in having these available for plan use. However, we previously commented on some issues that make use of the model notices prohibitive and we note that those issues still remain in these model notices. Our customers share our concerns and as a result we are unable to use these notices for virtually all of our business. We would suggest that the notices be revised and re-issued to include the following additional elements that are required by accreditation agencies (e.g., URAC and NCQA) or the existing ERISA claims regulation. Most utilization review entities hold these accreditations and will have to edit these elements into the model notices.

- Model Notice of Adverse Benefit Determination -- add the provider's right to a peer-to-peer discussion;

- Model Notice of Final Internal Adverse Benefit Determination -- add the reviewer's title and qualifications;

- All model notices -- add the right to obtain the benefit provision or guideline used in the decision process free of charge to the explanation section (existing ERISA requirement) alternatively, if the Departments' position is that this is covered under the 'Can I request copies of information relevant to my claim?' portion of the notices, we recommend that you clarify that the member can request the relevant benefit provisions or medical necessity criteria and not just medical information;

- All model notices -- add the timeframe to request the appeal and the turnaround time for a standard appeal; and

- All model notices -- add a placeholder for information that the claimant may provide to 'perfect the claim' (existing ERISA requirement).

In addition, both model notices appear to be missing the requirement that was just created in this amended IFR in 54.9815-2719T (E)(1) to include a statement describing the availability, upon request, of the diagnosis code and its corresponding meaning, and the treatment code and its corresponding meaning.

The amended model notices also create the potential for confusion with the appeal filing forms that contain a space for a member to designate an authorized representative and a space for the member's signature 'authorizing' the designation. While an authorized representative may request an appeal on behalf of the member, without a HIPAA-compliant authorization to disclose protected health information form we are unable to disclose the member's protected health information to this identified authorized representative. Simply designating someone as an "authorized representative" on an appeal form does not permit the identified individual to "stand in the shoes" so to speak of the member for purposes of HIPAA, and so we would still be required to correspond solely with the member. In order to avoid member confusion, we believe that there should be a notation on the form indicating that if the member wishes to have us communicate with the authorized representative regarding the appeal, the plan will need a valid signed HIPAA authorization form.

In addition, some of the requirements listed in the IFR appear to be repetitive of elements already contained in the ERISA claims regulation in § 2560.503-1(g) and (j). We would like some clarification on whether or not there is actually additional information required and, if so, what it is. For example:

> §2590.715-2719 (b)(2)(ii)(E)(2) requires a description of the standard used in denying the claim. Given that §2560.503-1(g)(iv) already requires plans to furnish any internal rule, guideline, protocol, or other similar criterion was relied upon in making the adverse determination, it is not clear what additional information is expected by the IFR requirement.

§2590.715-2719 (b)(2)(ii)(E)(2) requires a discussion of the adverse determination decision. It is not clear what is left for plans to discuss given the detailed requirements under the combined rules that plans furnish the specific reason(s) for the adverse benefit determination, the meanings of codes, the standard and internal rule, guideline, protocol, or other similar criterion applied, a description of information or materials that would perfect the claim along with an explanation of the need for that information or materials, identification of the applicable plan provision, and, as applicable, an explanation of the scientific or clinical judgment applied to the claimant's circumstances.

§2590.715-2719 (b)(2)(ii)(E)(3) requires a description of available internal appeals and external review processes, including information regarding how to initiate an appeal. Other than adding notice of the external review processes, it is not clear what additional information is expected from plans given that a description of the review procedures, the applicable time limits, and a statement of the right to sue under ERISA is already required in §2560.503-1(g) (iv).

If the Departments' intent was to set forth additional requirements with respect to the duplicative provisions, clarification of the intended meaning would be extremely helpful to enable plans to comply. If instead, the Departments' intent was only to amplify existing requirements, integration of the two sets of regulations and/or clarification of terms would eliminate the confusion and ambiguity resulting from the overlap.

Individual Plan Internal Appeal Process

We previously commented on the administrative burden for insurers to separate out individual plans from group plans in order to comply with the requirement that individual plans only have one level of internal review. The comments to the original IFR note on page 43334 that this one-level process is required because "There is no need for a second level of an internal appeal in the individual market since the issuer conducts all levels of the internal appeal." While the same entity may indeed conduct both levels of review in a two-level appeal design, our process (and that of most of our customers) is to use reviewers with no prior knowledge of the case to conduct each level of the appeal process. Having an additional independent reviewer evaluate the case does provide an opportunity for an unbiased and fair review and should be permitted for individual plans, not just group plans. We conduct specialty reviews for numerous insurers that include individual members in the business that we manage. Under these regulations, we have to create new processes to identify these individual members so that we can limit them to only one review, creating additional administrative work for us and the health plans while removing a level of review with the potential to benefit the members. We encourage the Departments to allow insurers the same discretion to offer either one or two appeal levels for individual plans as are available to group plans.

Verbal Notification

Given the expansion of information required in notices, plans should not be required to include all of the information in 29 CFR 2590.715-2719(b)(2)(ii)(E) and §2560.503-1(g)(1) in oral notices furnished under §2560.503-1(g)(2). For both plans and health care providers, the additional time in

prolonged telephone calls which would be needed in order to communicate all of the information required by the IFR is burdensome. Instead of mandating that all of the listed information be provided proactively in oral notices, we suggest that plans be required only to proactively furnish in oral notices the reason for denial and a description of the process for expedited appeal with the comprehensive information contained in the written notice.

We also request that the Department of Labor amend the regulation to permit verbal notification for the initial communication of urgent pre-service appeal determinations in section 2560.503-1(i)(2)(i) or 2560.503-1 (j), which would then be followed with the written communication. Doing so would allow a consistent process for handling expedited requests throughout the internal process and allow us to provide a more timely response to the claimants in these reviews.

Strict Liability Standard

We were pleased to see some exceptions to the strict liability standard in the amended IFR; however, we would urge you to modify this standard further. By requiring that de minimis violations be "for good cause or due to matters beyond control of the plan or issuer" (page 37231 29 CFR 2590.715-2719(b)(2)(ii)(F)(2)), plans remain at risk for any accidental violations irrespective of whether or not the violations posed any prejudice or harm to the member. Despite all preventive measures and all quality assurance efforts a plan can undertake, there is no way to prevent all mistakes and accidental violations. While we agree that plans, not members, should bear the consequences of accidental violations that harm members, we cannot see any reason that an accidental violation that does not harm a member should prejudice the plan. The language exculpating plans only 'for good cause or due to matters beyond control of the plan or issuer' will permit members in cases with even minor harmless error (e.g., letter mailed out one day late) to pursue remedies under ERISA, including a civil lawsuit. This could increase litigation costs for plans at a time where costs are escalating and plans and employers are struggling to rein in costs. We would ask that you modify the language to include minor errors on the part of the plan to be considered de minimis if there is no harm or chance of harm to the member from the violation, so long as the violation is not part of a continuing pattern.

We appreciate the opportunity to comment on these regulations, and look forward to your thoughtful and considered evaluation of the issues raised herein. If you would like further information on any of the issues raised in this letter please feel free to contact me at 410-953-4710 or tmberman@magellanhealth.com.

Sincerely,

Teresa Berman
Vice President and Associate General Counsel
Magellan Health Services