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Office of Consumer Information and Insurance Oversight **EXPRESS/OVERNIGHT MAIL**
Department of Health and Human Services
Attention: OCHO-9993-IFC
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Subject: Comments on 45 CFR Part 147, RIN 0991-AB70 – 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

The following comments are made both as a benefits consultant for over 40 years and on behalf of self-funded plans, specifically plan of unions and of non-federal governmental entities subject to PHS (not ERISA). The rules should provide additional protections for self- funded versus fully insured plans.

1. **Effective Date:** Plan Years beginning on or after September 23, 2010.

   Recommendation: Since the rules are incomplete and do not cover the Federal rules as they apply to self funded plans, the effective date for self funded plans should be delayed until Plan Years Beginning after 2010 or Plan Years beginning on or after 60 days following the publication of the Federal rules. It is extremely costly and burdensome to amend plans and to do it multiple times is even more costly, confusing and it should be unnecessary. The whole purpose is to lower medical costs and every single new requirement has the opposite effect—resulting in increased costs for Plans that are being reflected in the renewal rates we are seeing for new Health Care Compliant Plans. See also comment # 6. Even the State rules are not in place to comply with NAIC Uniform External Review Model Act issued April 2010 are no where close to being in place.

2. **Recision of Coverage:** Recision as the term is generally known is when an insurance company denies or cancels coverage retroactively based on medical conditions or misrepresentation at the time of the application. The regulations have attempted to inappropriately broaden this definition beyond what is stated in the law to include discontinuance of coverage which takes into account situations where a dependent or member is no longer eligible for such coverage. **The definition of Recision, Cancellation, or Discontinuance of Coverage needs to be modified to EXCLUDE the following:**
   - Loss of coverage due loss of eligibility due to no longer being eligible to be covered (e.g. a spouse due to divorce or legal separation);
   - Loss of eligibility due to reaching the maximum age for coverage as a dependent.

- Loss of eligibility to be covered as a disabled dependent due to loss of dependent status or other criteria for being covered as a disabled dependent, such as becoming covered under another plan, including Medicare.

Each of the above events has been and continues to be covered under and subject to COBRA rules. Under COBRA, the employer has 30 days to notify the administrator of a COBA event and members are REQUIRED to notify the Plan of certain changes in family status that may affect a member's eligibility for coverage, e.g. divorce, attainment of maximum age, loss of dependent status, acquisition of other coverage; and legal separation. **This is totally separate from situations where an insurance company is retrospectively rescinding coverage due to a pre-existing condition or failure to disclose certain medical information in the insurance application, etc.**

The Patient Protection and Affordable Care Act did not amend COBRA rules and COBRA rules should continue to govern the loss of coverage as there is an indisputable right on the part of the member to continue their coverage under COBRA when an individual(s) are no longer eligible due to loss of *"eligibility status"*.

Recommendation: These rules should stipulate that "failure of a member to timely inform the plan of a required COBRA event is presumed to be misrepresentation" and thus should not create additional liability for the Plan to provide coverage beyond the date of the event. **There must continue to be member responsibility and accountability for notifying the plan of any COBRA event or any event that changes the coverage status of a covered dependent.** For example, acquisition of other coverage, loss of employment, retirement, etc. may change the determination of which plan is primary and which plan is secondary. **It is common practice to make such changes effective as of the date of the event and the scope of this law should not cause coverage to be continued beyond any date when a plan is not legally required to provide coverage.**

If a Plan is required to provide extended coverage, than the Plan should also have the right to automatically charge the member the appropriate COBRA premium for any period of coverage after the Date of the Event and to recover such COBRA premiums directly or indirectly from any claims under the Plan. In no event should Plans have to pay extra for employee/member oversight—intentional or not!

3. **Benefit Determination:** The requirement that a plan or insurer notify a claimant of a benefit determination (whether adverse or not) with respect to a **claim** involving urgent care must be made no later than 24 hours after **receipt of the claim** is totally unreasonable. Large volumes of claims are received daily and they are not identified separately by the nature of the claim. It is totally unreasonable for any plan or insurer to be expected to process such claims within 24 hours of receipt in that claims are normally processed in the order they are received. Further there is no need for such a requirement. What is appropriate is to require that any "*request for precertification"* or *"approval of a specific procedure or service*" that would be considered *"urgent care"* request be responded to within 24 hours *(excluding weekends and holidays)*. The terminology in the regulations needs to be specific in this instance to distinguish between a *"claim"* versus a *"request"*. A claim is filed "after the fact"; and further, the final claim and how it is submitted will determine how the benefits will be paid since most precertification only provides approval of a particular service on the basis of medical necessity and does not involve approval of specific procedures codes and charges. Precertification is not a guarantee of payment or benefits as these are two distinct functions. For example, an individual could get a procedure approved and then due to a change in status be an ineligible member or employee at the time of the service, or the Plan's coverage could change from being the primary plan to the secondary plan due to a change in other coverage. To determine claim payment, the provider would have to submit an actual "estimated" claim which included

procedure codes, charges, etc. with appropriate provider information to determine whether or not the claim would be paid as in or out of network.

Recommendation: The rules need to clarify that weekends and holidays are excluded because it goes beyond the authority of this law to require a plan or insurer to provider Precertification and/or claims support 24/7, which would indirectly be the result of such a rule and which would create a tremendous increase in COST, especially for self-funded plans. In any event this rule should at a minimum exclude weekends and holidays for self-funded plans, and specifically, PHS Plans, as they generally would not have the 24/7 staff that many insurers are capable of supporting.

Non-English Requirements: We object in the strongest terms possible of ANY requirement to provide notices to members in a non-English language. This is the United States of America and the language of this country is ENGLISH. No Plan should be burdened with any requirement to provide any statements, services, etc. in a non-English language. This is unduly burdensome and serves only to increase medical costs--even for larger companies as there are easily hundreds of different languages spoken in the world and no entity should be expected to support various languages. While the law left the details to be defined in the regulations, a **threshold of the lesser of 500 or 10% of all the participants speaking the same non-English language for plans with over 100 lives is unreasonable and is cost prohibitive for most self-funded plans.**

Since this country was founded, immigrants have adapted by learning the English language. That standard should be encouraged not discouraged by burdensome government regulations. It is difficult enough for plans to attempt to put complex government legalese into readable, easily understood language in English, much less to duplicate such efforts for various non-English languages spoken by employees. It should be up to the individual to secure appropriate assistance from family members, local interpreters, or other agencies if assistance is needed in interpreting their group health plans, benefits, claims, etc. **It is the responsibility of individuals living in this country to learn to speak and read English.** Internationally, other countries are not attempting to accommodate and placate citizens who have not learned to speak the language native to that country.

Recommendation: Self-funded plans, especially non-ERISA or PHS Plans, should be exempted from any non-English SPD requirements. **Employers or insurers should not be responsible for supporting non-English languages in any plan where fewer than 25% of all the participants speak the same language. The 25% rule based on the language spoken by the Participants should be appropriate for all plan sizes as 10% if far too small of a percentage. These types of requirements increase the cost of compliance many times over when we need to be finding ways to DECREASE medical costs not INCREASE costs with additional BURDENSOME, COMPLICATED AND UNNECESSARY NEW RULES AND REGULATIONS.**

4. **Requirement Six:** To require that a plan not reduce or terminate an ongoing course of treatment without providing advance notice and an opportunity for external review PREVENTS a plan from employing and utilizing any medical necessity since this can be circumvented by appealing a decision. **These rules as written encourage abuse by providers and claimants by permitting them to delay the appeal request since there are no time requirements on the providers other than the 4 month period to appeal such a denial.** What is to prevent a provider from continuing treatment and then requesting a review towards the end of the 4-month period? **These rules diminish the standard medical necessity requirements which are essential in controlling plan costs. Again, these rules add additional cost and potential liability for plans.**

Also, what if the request for appeal is bogged down at the state or federal level? It is totally inappropriate to penalize the plan and require continued treatment because of such delays unless there is a guaranteed response from the state and federal bureaucracies (currently non existent) of 24 hour turnaround in terms of assigning and forwarding the appeal to an IRO. Then what about the IRO response time? The IRO findings could be delayed due to having too few approved IRO's and too many claims, leaving the plan with additional benefits and treatment that it should not have to pay if the treatment is not medically necessary or appropriate based on Plan rules.

Plans should have the option of requesting a Peer Review/External Review to substantiate their position when there is a question of medical necessity or appropriateness of care. In the case where a plan has obtained such an opinion from an approved IRO, benefits would not be covered beyond that determination date, or perhaps within no more than 24 or 48 hours of that date to permit appropriate time to discharge the patient after the provider is informed that the continuing care no longer qualifies for benefits.

Recommendation: **First,** such a rule should also include timely appeal requirements, e.g. that the appeal must be made within 24 hours following a denial **if the denial is in conjunction with ongoing treatment in order for treatment to be covered during the appeal period and all additional information must be provided within that time frame or within 48 hours maximum. Otherwise benefits would not be covered during the appeal period UNLESS the finding is that the continued treatment is medically necessary or appropriate based on review by IRO findings.** The final rules should also stipulate that treatment commenced after an initial denial will not be covered unless the initial denial is reversed based on a review by an IRO.

Secondly, there should be an exception to this rule whereby continued coverage during the appeal process is not covered during the appeal process when medical necessity or appropriateness of treatment denial was the subject of an independent external review by an IRO, initiated by either the Claimant or the Plan either as part of or in additional to the internal appeal rules.

Third, if upon appeal, the prior decision is reversed, and then coverage and benefits for such treatment will be adjusted and covered per the Plan. There should also be a provision whereby if the second review by an IRO contradicts the first, opinion, that there shall automatically be a third opinion requested from a different IRO in order to reach a final decision unless the Plan determines that it will abide by the previous decision in favor of the Claimant.

5. **Interim Final Rule:** We totally disagree and object to the Secretaries position that "proposed" regulations are not appropriate due to the "urgency" to implement Health Care Reform. Rather this RUSH to implement final regulations prior to giving the public an opportunity to comment is an overt attempt to circumvent the traditional practice of allowing public review and comments in advance of issuing any binding regulations. It is further most inappropriate to implement these new rules when there is no established State or Federal Review program in place. You are putting the cart before the horse and causing unnecessary duplication of efforts in that plans must attempt to comply with these rules and then will be forced to amend the rules as further guidance is issued. This is most costly and unfair to plans, especially self-funded plans.

   Recommendation: These regulations should be withdrawn and not implemented until they can be modified to incorporate public concerns and when appropriate mechanisms are in place at the state and federal level. It is unfair and unreasonable for the HHS Department to circumvent long established practice of issuing "proposed regulations" and them reissuing them in interim or final form AFTER the public comments have been reviewed and considered. The very fact that these regulations are

incomplete and additional regulations are to be forthcoming illustrates only a partial effort with respect to compliance with the new laws. This approach INCREASES COSTS AND IS UNDULY BURDENSOME TO PLANS to be forced to comply within such a short amount of time.

At a minimum, these rules should not be effective until Plan Years beginning AFTER 2010, especially for self-funded plans since they are subject to Federal rules and such rules were not issued in these regulations. The effective date for self-funded, especially non-ERISA Plans should be deferred until Federal rules are issued.

We further disagree with the Secretaries findings that it is impracticable and contrary to the public interest to delay putting the provisions in these interim final regulations in place until full public notice and comment process is completed. We believe that the Secretaries are usurping their authority and placing employers at risk inasmuch as employers are not even being given a sufficient time to review and understand these rules before they are to be effective. Never in the past, even when ERISA was passed, was there such a rush to mandate compliance without going through the proposed regulation process. These rules are unduly complex and there are additional burdens being placed on plans that go beyond the intent of the law and the scope of the Secretaries' authority. Further, this approach will be totally confusing to employees, employers and plans alike during the transition period with no state or federal rules in place. State rules will vary by state and such rules once adopted must be approved by HHS before those rules would apply? This whole approach is totally backward.

6. **External Review for Self Funded Plans:** While this was not covered under these rules, it is important that the appropriate considerations be given to the External Review Process. **There is absolutely no reason why the initial request for an external review cannot be submitted directly to the Plan. So long as the plan complies with using an authorized External IRO from the approved list maintained by the DOL it totally unnecessary to create yet another layer of bureaucracy to go through. Following the Uniform Health Carrier External Review Model Act and creating a similar nightmare at the Federal level for self funded plans would be totally wrong for self funded plans and would add unnecessary expense and bureaucracy.**

   Plans and Insurers are perfectly capable and willing to manage an equitable External Review Process independently and the SAFE HARBOR should be to permit a claimant or their representative to file an official appeal with the State of the Federal Agency only if the plan fails to follow the External Review procedures. The External Appeals should be approached more like COBRA and assess a daily penalty if a plan fails to follow through on Claimants rights to an External Appeal. At a minimum, the initial External Appeal should be handled at the Plan level.

   Quite frankly, our self funded plans voluntarily utilize and often initiate an external or peer review on troublesome medical necessity or appropriateness of care issues to be sure we have made the correct call. When needed we get a Second opinion from an IRO and would get a third if the second opinion differs from the first. This provides fairness to all parties and is relatively quick and would be far less complex and costly than some cumbersome new Federal bureaucracy. **The focus now is on having a sufficient number of IRO's approved coupled with a requirement that External Claims would have to be rotated among a minimum of 3 IRO's to insure there is no conflict of interest of established relationship that would bias the IRO in any decision.**

   In short, we need LESS REGULATION, LESS BUREAUCRACY AND FEWER REPORTS—not more. We need to do things that will REDUCE medical costs, not increase them, as these rules would do.

The regulations include the following language, which needs to be clarified. For example, it is our interpretation of the law that a non-federal government, self funded plan would be subject to Federal rules and not State rules. Is this not correct? The following language is ambiguous at best. **Does this mean that a self-funded, non-federal governmental/union plan could choose to comply with state vs. federal rules?**

> *These interim final regulations do not preclude a State external review process from applying to and being binding on a self-insured group health plan under some circumstances.* ***While the preemption provisions of ERISA ordinarily would prevent a State external review process from applying directly to an ERISA plan, ERISA preemption does not prevent a State external review process from applying to some self-insured plans, such as nonfederal governmental plans and church plans not covered by ERISA preemption, and multiple employer welfare arrangements, which can be subject to both ERISA and State insurance laws****. A State external review process could apply to such plans if the process includes, at a minimum, the consumer protections in the NAIC Uniform Model Act.*

Sincerely,

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