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VIA RULEMAKING PORTAL

Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-9993-IFC2

Office of Health Plan Standards and Compliance Assistance
Employee Benefits Security Administration
U.S. Department of Labor
Attention: RIN 1210-AB45

Internal Revenue Service
United States Treasury
Attention: REG-125592-10

Dear Sirs/Madams:

Thank you for this opportunity to comment on the June 22, 2011 regulations amending the July 23, 2010 interim final rules ("amending regulations" and "IFR," respectively). While we are pleased that many of the provisions of the IFR remain intact, we are concerned about several issues.

I. Medical Judgment

First, although the Departments rightly abandoned the "substantial compliance" standard of plan compliance with internal appeal rules in the IFR, and largely maintained the strict compliance standard in the amending regulations, the Departments introduced a new term – "medical judgment" – that is every bit as ambiguous as the "substantial compliance" standard has proven to be under ERISA. While the examples of "medical judgment" provided by the Departments are helpful, significant issues remain, and we foresee widely varying interpretation of that phrase by different external reviewers, even for the same plan. Most significantly, do coding errors involve the exercise of medical judgment? If the provider chose a code because he or she believed that it best fit the nature of the procedure, but the insurer disagreed with that coding, that could involve the exercise of medical judgment; whereas, if a clerical person simply assigned the wrong code to a procedure, no medical judgment will have been exercised. Will IROs then conduct evidentiary hearings to determine whether a coding error involved the exercise of medical

judgment? Realistically, what consumer, acting on his or her own, would be able to mount such a case?

We understand that the Departments were concerned with the capacity of IROs to address legal questions or questions of contract interpretation. However, those lines are not so easily drawn. For example, we had a case in which a patient needed a stoma revision. She had lost a lot of weight, so in order to repair her stoma, excess skin had to be excised. The insurer denied that portion of the surgery because it was coded as a "tummy tuck," which came under the exclusion of cosmetic surgery, making the issue one of contract interpretation rather than medical necessity. However, the "tummy tuck" was essential in order to repair the patient's stoma, making it a medical necessity issue – one on which we ultimately prevailed. Would all external reviewers understand this to be a medical necessity determination?

There is no need to introduce an ambiguous phrase. An IRO can hire an attorney just as easily as it can hire a physician if legal expertise is required. However, in most instances – like those described above – it is clear that the interpretation of the contract depends at least in part on medical factors. A coding error that is not resolved on internal appeal probably does require some medical decision-making; true errors generally are resolved on internal appeal. There simply is no compelling reason to introduce an ambiguous phrase that seeks to limit external appeal rights in ways that will only create another hurdle for consumers seeking independent review. We urge the Departments to reconsider the use of the "medical judgment" limitation on the scope of federal external review.

II. Language Access

While we are not experts in the law relating to clients with limited English proficiency (LEP), we strongly oppose the Departments' decision to limit interpretation and translation as it has done. By using a percentage of a county rather than a percentage of plan members, many people with LEP will not have access to the information they need to secure their rights to appeal and, ultimately, coverage. They will not understand denial notices or appeal instructions. We are aware that others will be addressing this issue in greater detail, so we will defer to the experts to suggest alternatives to the Departments. We simply want to urge the Departments to adopt a standard that more realistically addresses the needs of those with LEP.

III. State External Appeal

In providing a transition period during which states can comply with 13 minimum consumer protections rather than the 16 listed in the IFR, the Departments have provided that "States may not reduce the consumer protections in their external review process below the level that applies at the time HHS makes its finding" regarding the sufficiency of the State's external appeal rules. (Technical Release 2011-2). This is critical. Some states have come into compliance with the 16 consumer protections based on the belief that they were required to do so by the time HHS conducts its review. We know from our discussions with state officials that they would not have done so had they known they had a choice of sticking with more relaxed consumer protections. Those states should not be permitted to back-track. And although states now will have until 2014 to come into full compliance with the 16 minimum consumer protections listed in the IFR, they should be encouraged to comply with the IFR as quickly as possible.

IV. Plans' Choice of IRO

We continue to believe that allowing self-funded plans to contract with two or even three IROs rather than having some sort of mechanism by which IROs are selected at random is a mistake. IROs that work for a particular plan become the plan's vendor, relying on the plan for continued business. Thus, they lose their independence. They will know that their continued good standing with the plan will be based on their performance – and here, performance means reaching decisions in favor of the plan. Independence is a critical aspect of external review, without which the external review is not really external.

We have had the experience of the same IRO ruling on whether the same medical device is experimental/investigational, ruling in our favor when the IRO was contracted with a state, and ruling in favor of the plan when the IRO was contracted with the plan. This at least creates the appearance that the IRO – which reviewed the same medical literature in both cases (indeed, more literature in the case of the appeal from the decision of a self-funded plan, which was approximately two years later than the appeal from the fully-funded plan), pertaining to the same device used to treat the same medical condition – was biased in the plan's favor when it was selected and paid by the plan. This tells us that when plans select the IRO, the review loses its independence.

We can think of several alternatives. Self-funded plans could be directed to use state external review processes. A centralized list – perhaps at DOL or even at a non-governmental organization like URAC or an association like NAIC – of accredited IROs could be maintained, and IROs could be assigned at random. What should not be permitted is a situation in which IROs become "captive" of the plan.

V. Communications with Insurers/Plans

Finally, we wish to interpose a cautionary note regarding communications between plans/issuers and consumers that the Departments appear to believe may be conducted verbally rather than in writing. For example, the Departments are unclear whether, when a consumer requests diagnosis and procedure codes along with their explanation, this information will be provided verbally or in writing. Similarly, the Departments appear to contemplate that notices may be translated into other languages verbally rather than in writing. This is a huge problem.

We file many insurance appeals each year, so we have frequent contact with insurers/plans. We have learned over time that verbal communication is entirely unreliable, and insurers/plans are not accountable for errors they make in verbal communications. We have been told that appeals were granted or denied when they were not. We have been given the wrong address – repeatedly – to which to send an appeal. We have been told that we were granted an extension of time in which to file an appeal, and when the appeal was filed, it was rejected as untimely. We have requested estimates of the "maximum allowable amount" for an out-of-network service, and when the claim is filed, the estimate was completely ignored. We could go on.

Verbal communication with plans/issuers is utterly unreliable. There is no record of what was said (recordings are erased after thirty days by at least some companies), and if we cannot prove that we were given the wrong information, the insurer feels free to assume that we are not accurately portraying what was said. We have tried to confirm verbal conversations with follow-up letters, but since we have nowhere to address such letters other than a generic claims address or an appeals address despite the fact that the conversation occurred with a customer service representative, this strategy is fruitless. In

the end, it is the consumer who loses out if the information provided by the plan/issuer is incorrect but not in writing.

Thus, we strongly urge the Departments to require that all communications between consumers and plans/issuers are in writing. If a consumer calls for a translation and that translation is given verbally, it should be followed up by a written interpretation, as well. If a consumer requests diagnosis and procedure codes and their explanations, they should be asked whether they would like to receive this information by mail, email, fax, or secure internet portal; it should not be provided over the telephone, and if it is, it should be provided in writing, as well.

One of the most maddening aspects of working with plans/issuers is the inability to get the same person on the telephone twice, the chronic loss of documents that are mailed to the plan/issuers, and the volume of erroneous information that is provided verbally. The Departments have the opportunity to ensure that this last phenomenon is eliminated by requiring that all communications from plans/issuers be in writing, or at least be followed up with the same information in writing. We strongly urge the Departments to capitalize on that opportunity.

VI. Conclusion

We continue to believe that the heightened, more uniform appeal processes, including the requirement that self-funded plans offer external review, are one of the most exciting aspects of the ACA for consumers, at least among those provisions that have taken effect to date. It is critical that the Departments continue to stand strong in ensuring that the appeal rules fully realize Congress's intent to ensure that consumers have a meaningful opportunity to challenge adverse benefit determinations to the fullest extent practicable.

Sincerely,

Jennifer C. Jaff, Esq.[*]

[*] Admitted to practice law in Connecticut, New York and the District of Columbia. Advocacy for Patients is a 501(c)(3) tax-exempt organization and does not charge patients for its services. Advocacy for Patients is funded by, among other sources, grants from foundations and companies that engage in health care-related advocacy, manufacturing, delivery and financing. A list of grantors will be furnished upon request.