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Dear Ms. Borzi and Ms. Pollitz:

We, the undersigned consumer advocacy organizations, write to provide you with our viewpoint regarding several aspects of the new appeal procedures under the Affordable Care Act: external appeals in self-funded plans; the content of notices; language access; urgent care claims; and "substantial" versus "strict" compliance with the rules.

I. External Appeals in Self-Funded Plans

First, we urge the Department of Labor to stand firm for consumers in rejecting the position that the Secretary should "deem" existing second-level internal appeals offered by some self-funded plans as sufficient to meet the Affordable Care Act's mandate that all consumers have the opportunity for an external review process that "at a minimum, includes the consumer protections in the Uniform External Review Model Act promulgated by the National Association of Insurance Commissioners" ACA § 2719.

In our experience, there are many self-funded plans that do contract with physicians or organizations that employ physicians who review plans' coverage decisions. However, this is not an external review as established by the NAIC Model Act. A true external review, which exists in many States, operates independently of the insurer or plan. The consumer sends the request for external review to a State agency; the State agency chooses an independent review organization (IRO) at random out of several possible IROs; the IRO conducts the review, taking both the consumer's and the insurer's or plan's position into account; and the IRO decision is then sent to both the consumer and the insurer or plan, and is binding on the insurer or plan. A process that departs from these basic constructs cannot provide the independence necessary for the external review to serve as a genuine check on the insurer or plan's policies and practices.

Independence is absolutely essential to a functional external review. We know, for example, that when insurers or plans act as the hub, receiving the appeal, choosing the outside reviewer, receiving the decision of the outside reviewer, and then issuing a decision to the consumer, outcomes are skewed in favor of insurers or plans. For example, an investigation in Illinois found that insurers were calling so-called IROs and complaining about particular medical reviewers, asking that those physicians no longer review the insurer's claims, thereby directly and unduly influencing outcomes. We also can cite cases in which an IRO ruled in favor of consumers in true external appeals administered by States, but the same so-called IRO ruling on the same treatment for the same condition ruled for the plan when the outside reviewer was selected by the plan. Outside reviewers who become "captive" to the plan rule in favor of the plan. The final rules must guard against this; and the Secretary should not "deem" a process lacking in independence to be sufficient under the ACA.

Not only are outcomes affected by a lack of independence, but the quality of the outside reviewer's analysis also is affected by how closely its interests are aligned with those of the insurer or plan. Most insurers and third-party administrators have clinical

policy bulletins, some of which are deeply flawed, representing quoted abstracts that may be inaccurate and/or out of date. "Captive" outside reviewers may not go further than to rubber stamp the application of the clinical policy bulletin to the facts of the particular case. However, a truly independent external reviewer would do his or her own literature search and analysis, and would issue a decision that reviewed the consumer's medical history and analyzed the medical literature with an entirely fresh – and competent – pair of eyes.

Further, in order to achieve true independence, external reviews must be *de novo*, and no deference should be shown to the plan administrator, as is set forth in the NAIC Model Act. An external reviewer should view the file anew, with fresh eyes and an unbiased viewpoint. The question is not whether there is any rationale pursuant to which the plan's decision can be upheld; it is whether the plan's decision is correct. Paying deference to what may well be an erroneous decision would only repeat the plan's error, if in fact one has been made. *De novo* review provides the best opportunity for accurate, unbiased outcomes.

The second-level internal appeals that self-funded plans wish the Secretary to deem sufficient lack not only true independence, but also transparency. Consumers have no way of knowing how the reviewer was chosen, who the reviewer was, or even what the reviewer actually said. In most cases involving self-funded plans, the decision is reported by the third party administrator or the plan itself. It references and reports the reviewer's decision, but a copy of that decision is not provided to the consumer. Appeals that consist of hundreds of pages of medical records and medical journal articles may be denied in a paragraph or two, and since these often are the final word because many consumers cannot proceed to court for a whole host of reasons, the consumer is left wondering whether their appeal even was read.

In short, we believe that both independence and transparency are essential. If plans are going to be allowed to administer their own "external review" process, they should be required to contract with more than one IRO; they should be precluded from discussing the case with the IRO except in writing; a copy of any written communication should be provided to the consumer, with an opportunity to respond; and the IRO's decision in full should be provided to the consumer. The plan should not be allowed to frame questions such as: "Please review this case to determine if [the plan] applied its Medical Policy correctly," since that entirely avoids the question of whether the Medical Policy is itself correct. The IRO should review the insurer's or plan's file and the consumer's appeal, do its own research when appropriate, and issue a thorough decision that allows both parties to feel confident that the review was performed independently and conscientiously. This is the intent behind the plain language of the ACA; and this is the bare minimum that is necessary to ensure that external reviews are meaningful.

Finally, we cannot overstress the importance of the IRO's decision being binding on the insurer or plan. All of the independence and transparency gets us nowhere if a plan can simply veto the external reviewer. Allowing a plan to overrule an external reviewer not only is inconsistent with the Congressional language that refers to the NAIC Model Rule, but it also vitiates the protections that external review provides, frustrating clear Congressional intent. The external reviewer's word must be final and binding.

II. Content of Notices

Second, we understand that there are concerns about whether confidentiality is breached by including a significant amount of personal medical information in EOBs and denial letters. However, we also know that consumers need access to enough information

to afford them a meaningful opportunity to appeal. These interests should be balanced in a way that maintains confidentiality in the event the EOB were to be opened by anyone other than the patient, while at the same time ensures that consumers – many of whom never have had to appeal an insurer's decision before – know what information to ask for if all of the necessary information is not included in the EOB or denial letter. In addition, although this should go without saying, the Departments should enforce consumers' interest so that insurers and plans cannot construe this request for information as the initiation of the appeal itself. This erroneous and violative practice has been pervasive, and is very difficult for consumers to reverse when it occurs.

III. Language Access

With respect to translation of written communications into other languages, our sense is that insurers and plans that are balking at this are, at least to some extent, exaggerating the burdensomeness of this requirement. They would prefer to interpret orally rather than provide written notices translated into an enrollee's language. Oral interpreting seems to us to be far more expensive since expenses for interpreters would be incurred for each individual needing assistance. Having a set of templates prepared in each language that meets the regulation's thresholds, with only the patient-specific information having to be translated on an individualized basis, is likely more cost-effective. In addition, quality control is far easier when communications are in writing. The "paper-trail" is also critical to ensure appropriate notice. If oral communication is allowed, will a plan meet the requirement by leaving a message on an enrollee's answering machine? If the plan is unable to reach the enrollee within the time frames, are the timeframes waived and how does this impact the enrollee's rights? And what if an enrollee does not have a telephone or shares a telephone with multiple individuals with whom the enrollee would not want health information shared?

Insurers and plans also complain that they do not know how to identify which insureds need translation into which languages. It would be simple enough to simply ask on enrollment forms whether translation of written communications is necessary, and in which languages. Most Medicaid and CHIP applications already do this and many have provided comments that the common application for the Exchanges should also collect this language. Further, most small businesses know if they have non-English speaking employees, and the native language of those employees, and they can furnish that information to the insurer or TPA.

While we agree that including "taglines" on notices in multiple languages is helpful when insurers and plans do not have language specific information, this places a burden on insureds to affirmatively call the insurer/plan to get additional information. Taglines should not be a compromise or option for plans but rather supplement the requirements to provide translated notices to ensure that insureds whose language needs are not noted are also informed of their rights.

Ensuring that people have the information they need means ensuring that they have access to that information in a form that they can comprehend. We simply do not agree that this requirement is unduly burdensome. Further, insurers or plans that operate in California are already subject to similar requirements under state law. And any plan or insurer that participates in Medicaid, CHIP or Medicare should be translating notices for frequently encountered languages pursuant to Title VI of the Civil Rights Act of 1964 (see the HHS "LEP Guidance" at www.lep.gov). Weighed against the benefits of providing accessible information, the scale clearly tips in favor of translation.

IV. Urgent Care Claims

Next, it is our understanding that insurers and plans are opposed to a 24-hour deadline for deciding urgent care claims, preferring, instead, a 72-hour window. The preamble to the interim final rules explains the Departments believe that electronic communication has evolved to the extent that information can be conveyed, and decisions can be made, far more quickly than they could in 2000, when the original DOL regulation providing the 72-hour window was promulgated. There is an exception to the 24-hour requirement when the claimant has not provided all of the necessary information to the insurer or plan.

These claims are, by definition, "claim[s] for medical care or treatment with respect to which the application of the time periods for making non-urgent care determinations could seriously jeopardize the life or health of the claimant or the ability of the claimant to regain maximum function; or, in the opinion of a physician with knowledge of the claimant's medical condition, would subject the claimant to severe pain that cannot be adequately managed without the care or treatment that is the subject of the claim." 29 C.F.R. § 2560.503-1(m)(1). Thus, they should be relatively rare, and in every case, time genuinely is of the essence.

V. Substantial Versus Strict Compliance

Finally, the interim final rules provide that, when an insurer or plan fails to "strictly" adhere to the requirements of the internal claim and appeal process, the consumer is deemed to have exhausted the internal appeal process and can pursue external review, regardless of whether the insurer or plan substantially complied with the regulatory requirements or whether any error is *de minimis*. Insurers and plans would prefer a "substantial" compliance standard to a "strict" compliance standard.

This is not an overly punitive provision. The claim or appeal is not deemed approved; the deeming affects only the ability to pursue remedies outside of the plan. In light of the delays suffered by consumers, this standard is entirely appropriate.

Time and time again, insurers and plans lose, delay and even ignore internal appeals. If the consumer is represented by a third party and the third party submits a HIPAA release and authorization on its own letterhead rather than on a form buried on the insurer's website, insurers may either ignore the appeal entirely or fail and refuse to communicate with the consumer's representative. Over and over, appeals are lost or mistaken for a provider's appeal, so no notice of denial is sent to the consumer, and the opportunity to file a second-level or external appeal is greatly delayed. Consumers who failed to appreciate the likelihood that they would have to prove that they filed an appeal and, thus, did not send the appeal with a tracking mechanism (certified mail, delivery confirmation, etc.) have no recourse in the face of an insurer's assertion that it never received the consumer's appeal. At times, the insurer or plan fails to provide an address – or a correct address – to which to send an appeal, requiring that it be sent over and over again until it finally is received. Indeed, these sorts of unjustifiable delays are one of the most vexing issues in filing insurance appeals. And insurers and plans alone have the ability to remedy these delays. Strict compliance is entirely within the insurer's or plan's control.

The "substantial" compliance standard involves great ambiguity and subjectivity as to what is "substantial." Indeed, courts do not even agree on whether the question of

whether a plan has substantially complied is a question of law or of fact. *Compare Ponsetti v. GE Pension Plan*, 614 F.3d 684 (7th Cir. 2010)(question of fact) *with Baptist Memorial Hospital – DeSoto, Inc. v. Crain Automotive, Inc.*, 392 Fed. Appx. 288 (5th Cir. 2010) (question of law). What constitutes substantial compliance is a question as to which the courts have not reached agreement; the courts articulate the standard slightly differently. *See, e.g., Simonia v. Glendale Nissan/Infinity Disability Plan*, 378 Fed. Appx. 725 (9th Cir. 2010) (substantial compliance exists in the absence of prejudice to the claimant); *Estate of Thompson v. Sun Life Assur. Co. of Canada*, 354 Fed. Appx. 183 (5th Cir. 2009) (substantial compliance exists if the violation was technical and the insured has a meaningful opportunity for review); *Larson v. Old Dominion Freight Line, Inc.*, 277 Fed. Appx. 318 (4th Cir. 2008) (substantial compliance exists when plan administrator provides a sufficiently clear understanding of the administrator’s position so as to permit effective review). A strict compliance standard is far easier to enforce in that this same ambiguity and subjectivity is eliminated.

VI. Conclusion

We very much appreciate being involved in this ongoing dialogue to ensure that the ACA provides consumers with all of the protections that Congress intended. If you would like any additional discussion or information, please do not hesitate to contact us at patient_advocate@sbcglobal.net or cparcham@familiesusa.org.

Sincerely,

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