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September 15, 2010

VIA ELECTRONIC SUBMISSION

Office of Consumer Information and Insurance Oversight
Department of Health and Human Services
ATTN: OCCIO-9993-IFC
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, CT 20201

Office of Health Plan Standards and Compliance Assistance
Employee Benefits Security Administration
Room N-5653
U.S. Department of Labor
200 Constitution Avenue, NW
Washington, DC 20210
ATTN: RIN 1210 – AB45

CC: PA: LPD: RP (REG-125592-10)
Internal Revenue Service
1111 Constitution Avenue, NW
Washington, DC 20224

Dear Sir/Madam:

Thank you for this opportunity to comment on 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.

Advocacy for Patients with Chronic Illness, Inc. is a 501(c)(3) nonprofit that provides free information, advice and advocacy services to patients with chronic illnesses nationwide. Of particular significance here, we file free insurance appeals nationwide. Thus, we are one of the few organizations in the United States that has had the experience of filing both internal and external appeals in most States, as well as with many self-funded plans, including some of the largest in the United States. Our vast experience in thousands of cases informs these comments.

We applaud the thoughtful approach taken by the Agencies in formulating these complex rules. We are very impressed with the level of detail and expertise that the Interim Final Rules embody. Our comments should in no way imply dissatisfaction or disagreement with the Agencies' general approach. We write only to suggest additions and modifications that are based on actual experiences we have had in filing appeals across the United States.

For our organization and our clients, these rules, and the comments below, have critical importance. Because we file so many insurance appeals nationally, our experience is a strong indicator of the experience of other consumers and consumer-based organizations. Because our work is national, our ability to compare and contrast the actions of different insurers, plans, and independent review organizations in different States is exceptional. The very specific comments we provide below are not in response to hypothetical or theoretical practices; everything we discuss below has a real world reason and real world significance, based on our actual experiences. We hope that the following comments, in which we share our experience, will be helpful to the Agencies in further refining the rules.

Definitions

1. We support the use of a broad definition of "adverse benefit determination" to include eligibility decisions, coverage decisions, pre-existing condition exclusions, medical necessity determinations, determinations that a service is experimental or investigational, and rescissions. However, the definition of this phrase in the National Association of Insurance Commissioners Uniform Health Carrier External Review Model Act (NAIC Model Act) is narrower in that it does not include rescissions. Therefore, it is unclear whether State external appeals must include rescissions. While the rules use the phrase "adverse benefit determinations" in the context of discussing State external appeals, 26 C.F.R. § 54.9815-2719T(c)(2)(i), 29 C.F.R. § 2590.715-2719(c)(2)(i), 45 C.F.R. § 147.136(c)(2)(i), because the rules also essentially incorporate the NAIC Model Act, there is a latent ambiguity on this point.¹ We recommend that the Agencies clearly state that the definition set forth in the rules is intended to govern in every instance in which the phrase "adverse benefit determination" is used.

2. In addition, we strongly urge the Agencies to consider establishing and defining the phrase "medically appropriate off-label use" as a basis for coverage. In our experience, the vast majority of experimental/investigational denials in fact are denials of coverage of off-label uses of drugs and devices.² Rather than process these adverse benefit determinations as experimental uses when, in fact, they may be well-established uses supported by years of clinical practice, the reason for the denial should be stated more accurately, thereby allowing the consumer to focus on the medical appropriateness of the drug or device in the particular case rather than trying to prove that the drug or device is not experimental, which requires medical or scientific evidence. Vermont defines "medically

¹ The Rules related to federal external appeals expressly incorporate the definition of "adverse benefit determination," so there is no ambiguity with respect to federal external appeals. 26 C.F.R. § 54.9815-2719T(d)(1), 29 C.F.R. § 2590.715.2719(d)(1), 45 C.F.R. § 147.136(d)(1).

² An off-label use is the use of a drug or device for a use other than that for which it is FDA approved. To give a simple example, if the approved use of aspirin were to address pain, the use of aspirin to prevent heart attacks would be considered off-label.

appropriate off-label use of a drug" to mean "the use of a drug pursuant to a valid prescription by a health care provider where the drug is reasonably calculated to restore or maintain the insured's health, prevent deterioration of or palliate the insured's condition, or prevent the reasonably likely onset of a health problem or detect an incipient problem" Vt. Admin. Code § 4-5-4.7(A)(3). This appears to us to be an easier standard to meet than the experimental/investigational standard in that it can be proven through medical records without extensive medical research, and it is a more appropriate rationale for denial if the drug or device already is FDA approved for one use and it is being prescribed for another use. Thus, we urge adoption of this phrase and the accompanying definition.

Notices

1. Although this is contrary to every applicable State and Federal law of which we are aware, there are insurers and plans who tell consumers that they are not entitled to be represented in their insurance appeal, even by counsel, that only an appeal from the patient will be accepted, or that only an appeal from a physician will be accepted. Thus, we strongly urge you to require issuers and plans to include in the notice of adverse determination the consumer's right to be represented by a third party, including counsel, in both internal and/or external appeals.

2. Again, although this is not required or sanctioned by any State or Federal law, several issuers and plans refuse to communicate with a third-party representative based on a fully HIPAA-compliant release and authorization unless that release and authorization is on the issuer's/third-party administrator's letterhead, but they do not inform consumers of this fact in their notices, nor do they communicate this to either the consumer or his/her representative upon receipt of an appeal. Some insurers simply ignore appeals they receive from a consumer's representative without a release and authorization on the insurer's letterhead, and others communicate only with the consumer, even if the consumer has a representative.

By rights, issuers/plans should not be allowed to ignore a release and authorization that is substantively identical to the issuer's/plan's release and authorization simply because it is not on the issuer's/plan's letterhead.³ However, if an insurer or third-party administrator is going to require use of their own release and authorization form, they should provide a blank form as part of their notice of adverse decision. If they receive an appeal from a person claiming to represent the consumer without the issuer or third-party administrator's form, they should send the form to the consumer, with a copy to the consumer's representative, along with a letter informing the consumer that the appeal has been received, and instructing the consumer to fill out the form giving the issuer/plan authorization to communicate with the consumer's representative.

Once a third-party representative has "appeared" for the consumer by submitting a release and authorization acceptable to the issuer/plan, any and all further communications should be addressed to the representative in addition to the consumer. An "appearance"

³ In some States, this sort of gamesmanship is expressly prohibited. For example, in Vermont, an external appeal that is not submitted on the State's forms still must be accepted as long as it complies with the law in substance. Vt. Admin. Code 4-5-4:6(C). This should be the law in all States, not only with respect to external appeal forms, but with respect to all forms, including HIPAA releases and designation of representative forms.

that is accepted for purposes of an appeal should be entered in the plan/insurer's computer so that, if the third-party representative calls to check on the status of the appeal, the representative's authorized status will be apparent.

3. We understand that this, too, should go without saying, but it does not: Issuers and plans should include in their notice the correct address to which an appeal should be sent. If an insured or his/her representative has proof that the appeal was sent to that address in a timely manner, the appeal should be considered timely filed even if the issuer or plan claims that it did not receive the appeal. If the consumer has proof that the appeal has been submitted as directed several times and the issuer/plan still claims not to have received it, the appeal should be deemed granted.

We recently prevailed in an appeal that we had to send out three times, each time to another address to which the insurer directed us. Each time, we were told that the insurer did not have our appeal despite the fact that we had delivery confirmation from the United States Postal Service. This happens routinely, and it is unfair to consumers, not only because of the cost of shipping a 350+ page appeal three times, but also because of the delay this causes in getting treatment for the consumer. Issuers and plans should have to stipulate the correct address for filing an appeal in the notice of adverse determination. After an insurer has given a consumer several addresses and still denies receipt, the appeal should be deemed granted.

4. In a related point, we also recommend that issuers/plans be required to mail the person filing the appeal (consumer, provider, or representative) an acknowledgement of receipt of the appeal. For example, New York requires that the issuer/plan provide written confirmation of receipt of an appeal within fifteen days of receipt, Oregon requires confirmation of receipt of an appeal within seven days, and Indiana requires confirmation of receipt of an appeal within three days. N.Y. Ins. Law § 4904(c); Or. Admin. R. 836-053-1100(1)(a); Ind. Code § 27-13-10-7. This is critical so that consumers do not mistakenly sit on their rights, only to learn later that their appeal was not logged in and processed.

For example, we are working with a client who has lung cancer. She is on a protocol of Avastin and Alimta. Her insurer believes Avastin must be used only with either carboplatin or paclitaxel, not with Alimta. We filed an appeal on March 18, 2010. After not receiving a decision for some time, we called to ensure that the appeal was received. We were told that it was. We waited another month, called again, and were told that the appeal had been sent out for external review. We waited another month, called again, and were told that the appeal had been denied and a letter had gone out on August 12, 2010, five months after the appeal was filed. We called after another ten days and were told that the insurer would send another copy of the letter. When we finally received the August 12, 2010 letter, we immediately realized that it was not a response to our appeal but, instead, was a denial of coverage of Avastin for different dates of service. We still do not have a ruling on our appeal. Meanwhile, the health care provider has sent the claim to collections.⁴ At this point, we cannot even be certain that the appeal was logged into the system. All we have is a delivery confirmation from the U.S. Postal Service. Had the insurer been required to notify us of receipt, we at least would have proof that the appeal was received and logged in. It would come as no surprise to us, based on our experience, if the insurer were

⁴ Some states – for example, Massachusetts – do not allow claims to be reported to credit agencies during the pendency of appeals. Mass. Gen. Laws ch. 176O § 14(f).

to tell us that it mailed a decision months ago that we never received, and that all time periods to file subsequent appeals have passed, as discussed in the next paragraph. After waiting for five months and being given incorrect information repeatedly, the appeal should be deemed granted.

5. If a consumer does not receive a notice of adverse benefit determination, the time period during which an appeal must be filed should be tolled and extended. If a consumer does receive a notice of adverse benefit determination, the consumer should be able to rely on the date on the notice for calculating the appeal period.

We recently had a case in which Blue Cross Blue Shield of Delaware claimed to have mailed a notice in February 2010, but neither the consumer nor the provider who filed the first-level appeal received that notice. In April 2010, the consumer called Blue Cross asking about the status of her appeal. She was told that the appeal had been denied. Blue Cross agreed to send her a denial letter. Blue Cross sent a denial letter dated April 29, 2010 that said that she had 60 days to file an external appeal. We then agreed to represent the consumer and filed the external appeal within 60 days of receipt of the April 29, 2010 denial. Upon receipt by the issuer, the issuer refused to process our external appeal because the issuer claimed to have sent a letter to both the consumer and the health care provider in February, so the time to file the external appeal had expired by the time the consumer called to check the status of her appeal in April, before we agreed to take the case. We spoke with the Delaware Department of Insurance, which refused to overturn Blue Cross even though there was every indication that neither the consumer nor her doctor's office had received a denial in February. Essentially, then, the consumer was deprived of her right to file an external appeal because she never received the February notice of adverse decision, and she was unable to rely on the April notice of adverse decision in filing the external appeal within 60 days of the date of that notice. The rule should provide that (a) if the consumer credibly states that he or she did not receive a notice of adverse benefit determination, the time period during which to file subsequent appeals should be tolled and extended; and (b) if a consumer receives a notice of adverse determination, he or she should be able to rely upon the date on the notice for calculating the appeal period.

6. The NAIC Model Act at section 8(c)(2) provides that, if preliminary review of an appeal indicates that it is incomplete, the issuer is required to notify the claimant and explain what information or materials are needed to make the request complete. This is a very important consumer protection. In 2003, the Maryland Insurance Administration indicated that 14% of medical necessity appeals were rejected because the consumer failed to provide necessary information. According to a 2005 New York State External Appeal Program annual report, 178 of 667 external appeals that were rejected – 27 percent – were rejected because the consumer failed to provide necessary information. Thus, we would urge the Agencies to add a notice providing the consumer with an opportunity to cure in both internal and external appeals.

7. We recommend that you consider some of the provisions of Maryland Insurance Code Ann. § 15-10A-02(f), which requires that the notice of adverse decision be in clear language and "reference[] the specific criteria and standards, including interpretive guidelines, on which the decision was based, and may not solely use generalized terms such as 'experimental procedure not covered,' 'cosmetic procedure not covered,' 'service included under another procedure,' or 'not medically necessary.'" The elimination of the use of these

sorts of generalized terms would greatly advance the ability of consumers to understand the reason for a denial, thereby better focusing their appeal.

Similarly, the requirements for the Massachusetts notice of adverse benefit determination are exemplary. In Massachusetts, the notice must include a substantive clinical justification that is consistent with generally accepted principles of professional medical practice, including but not limited to (1) identifying the specific information upon which the adverse determination was based; (2) discussing the insured's presenting symptoms or condition, diagnosis and treatment interventions and the specific reasons such medical evidence fails to meet the relevant medical review criteria; (3) specifying alternative treatment options covered by the carrier, if any; (4) referencing and including applicable clinical practice guidelines and review criteria; and (5) notifying the insured or the insured's representative of the proceedings for requesting external review. Mass. Regs. Code tit. 105 § 128.307(B). These requirements ensure that consumers will have a full appreciation of the basis for the adverse decision, enabling them to focus their appeals accordingly.

8. Finally, we strongly urge you to require the issuer/plan to state in the notice of adverse determination whether it believes the plan is grandfathered pursuant to §§ 1251 and 10103 of the ACA and § 2301 of the Reconciliation Act, and, thus, exempt from these rules. Otherwise, it will be impossible for consumers to determine when these rules apply. This is absolutely critical.

Internal Appeals

1. The Agencies have chosen to require only one level of internal appeal even though the DOL claims procedures set forth in 29 C.F.R. § 2560.503-1 requires two levels of internal appeal. You have reasoned that

[t]here 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, unlike in the group market, where a third party administrator may conduct the first level of the internal appeal and the employer may conduct a second level of the internal appeal. Accordingly, after an issuer has reviewed an adverse benefit determination once, the claimant should be allowed to seek external review of the determination by an outside entity.

75 Fed. Reg. 43334.

The tacit assumption inherent in the Agencies' reasoning is that there never is value in an issuer or third-party administrator taking a second look at a case. We disagree. For example, there are insurers who, for at least some plans, provide a hearing at the second level appeal, and that can make a tremendous difference. We recently had a case involving a small group fully-funded plan through UnitedHealthcare involving deep brain stimulation for Tourette's syndrome – an off-label use for which there is significant clinical and scientific support. We lost the first level appeal and filed a second level appeal with UnitedHealthcare, at which point we were permitted to address the panel that would be voting on our appeal. Although the hearing was conducted telephonically rather than in person, it provided us with an opportunity to explain why we thought our particular case

presented a compelling case for an exception.⁵ Both the undersigned and the patient's father spoke to the appeal panel. Within only a few hours, we received word that we had prevailed. Had we not had the second level appeal, we would have had to pursue an external appeal. Although we would like to think we would have prevailed there, too, we simply do not know.

However, we also agree that there are cases in which a second level appeal to an issuer or third-party administrator is a waste. Recently, we had such a case involving a national plan through Anthem Blue Cross and Blue Shield. In that case, which involved a new, off-label use for a biologic, we lost the first level appeal and I asked the insurer if we could waive the second level internal appeal because there was no reason to think that Anthem would change its position. We were told that, if the consumer signed a waiver, we could proceed directly to external appeal. The consumer waived the second level internal appeal, we proceeded to external appeal, and we prevailed there.

Thus, rather than eliminate the requirement of two levels of internal appeal, we urge the Agencies to permit a consumer to waive the second level of internal appeal and proceed directly to external appeal. *See, e.g.,* Vt. Admin. Code § 4-5-3:10.300(C)(managed care grievances). This is a better resolution than one that eliminates the second level appeal in all cases, not only because it allows the consumer rather than issuer or plan to decide whether or not to eliminate or waive the second level appeal, but it also recognizes that, even though the rules may not require more than one level of appeal, some issuers/plans will continue to provide two levels of appeal, in which case the consumer should have a right to waive the second level appeal. Providing for waiver by the consumer rather than elimination by the insurer of the second level internal appeal is the best rule to protect consumers.

2. In another suggestion that may seem unnecessary, but that grows out of genuine problems we have had in quite a few cases, the rules should make it absolutely clear that requesting a copy of the file pursuant to either the DOL claims procedure, 29 C.F.R. § 2560.503-1(h)(2)(iii), or 26 C.F.R. § 54-9815-2719T(b)(2)(ii)(C)(1), 29 C.F.R. 2590.715-2719(b)(2)(ii)(C)(1), 45 C.F.R. § 147.136(b)(2)(ii)(C)(1), cannot be counted as the first level internal appeal. We acknowledge that, in a perfect world, the Agencies would not have to say this; the DOL claims procedure and the interim final rule clearly contemplate that a consumer can request a copy of the file without losing the right to appeal. However, on countless occasions, we have had to fight with issuers and plans on just this point. Indeed, this occurs more often than not whenever we request a copy of the file.

In addition, a request for a copy of the file should be responded to in full within a pre-determined period of time, or, at the very least, the time period in which to file an appeal should be tolled. We have had at least two recent cases in which we requested a copy of the file, it did not come within the appeal period, we filed the appeal regardless so as not to miss the filing deadline, and then a copy of the file arrived after we had filed the

⁵ Some States provide for an opportunity to communicate either in person or by telephone with the decision-makers on a second level appeal. *See, e.g.,* Vt. Admin. Code § 4-5-3:10.300(C)(6)(managed care). Pennsylvania requires that a second level appeal be heard by at least three people, and one-third of the panel members may not be employees of the insurance company. 40 Pa. Stat. Ann. §991.2141.

appeal, when it was too late to respond to any material in the file that warranted response. The rules should be amended to provide either that a copy of the file must be sent to the requestor (the consumer or his/her representative) within ten (10) business days, or that the time for filing an appeal is tolled when a request for the file is submitted, until the issuer or plan responds by sending a copy of the requested file.

Finally, there should be some consequence to the issuer/plan of ignoring a request for the file, including a request for a copy of the certificate of coverage or summary plan description. In the case of one extremely large nationwide insurer and third-party administrator, management recognized that nobody was responding to our requests – they simply were being ignored – so it assigned a person who works in the executive offices of the insurer/third-party administrator to respond to our requests for copies of files. While this is nice for us and our clients, it does not help the millions of other consumers insured by or through this company. All consumers should be able to obtain a copy of the insurer/plan's file, including the certificate of coverage or summary plan description. The failure to comply with this rule should carry with it a consequence that is of sufficient significance so as to provide the insurer/plan with an incentive to respond to these requests as a matter of course, as the law requires.

3. Similarly, a letter from a consumer stating that the consumer intends to appeal should not be counted as the appeal. Again, all too often, consumers receive a denial of coverage and immediately write a letter stating that they intend to appeal. Later, they submit medical records and other materials only to be told that they already have appealed. At times, they even receive a denial letter before they have sent the additional materials, although their intent to submit additional records is clear from the face of their initial letter.

Likewise, on several occasions, we have seen consumers write a letter stating an intent to appeal and submit additional documentation at a later time based on the mistaken belief that they can comply with an appeal deadline by so doing, thereby buying themselves more time to submit additional documentation after the time to appeal has expired. Of course, this is not the case; filing a letter stating an intent to appeal at a later date does not toll the deadline for filing the appeal.

These problems should be addressed by requiring issuers and plans to state in the notice of adverse determination that the consumer need not state an intent to appeal prior to doing so, but if the consumer intends to appeal, he or she must do so – including submitting all accompanying records – within the appeal deadline.

4. We very strongly support the protections set forth in 26 C.F.R. § 54.9815-2719T(b)(2)(F), 29 C.F.R. § 2590.715-2917(b)(2)(F), 45 C.F.R. § 147.136(v)(2)(F). In particular, when a plan or issuer fails to adhere strictly to the requirements with respect to providing notice and full and fair review, the claimant should be deemed to have exhausted the internal claims and appeals process. It is of particular importance that the rules state that if a claimant chooses to pursue remedies under Section 502(a) of ERISA in such circumstances, the appeal is deemed denied without the exercise of discretion so there will be no deference paid to the plan administrator. Similarly, with respect to appeals involving ongoing treatment, we very much support the provision that a plan and issuer must provide continued coverage pending the outcome of an appeal. These are critical consumer protections that place the burden of full compliance on issuers and plans, who have the

ability to comply promptly and completely, rather than on consumers, who are at the mercy of plans and issuers.

External Appeals

1. The rules provide that the State external appeal process must ensure against IRO conflicts of interest. 26 C.F.R. § 54.9815-2719T(c)(ix), 29 C.F.R. § 2590.715-2917(c)(ix), 45 C.F.R. § 147.136(c)(ix). We support this rule, but ask that the Agencies consider addressing a very specific circumstance that has arisen more than once in our practice. There are companies that write and sell clinical coverage policies to insurance companies and third-party administrators, and some of those companies also contract with States and plans to serve as independent review organizations. It is our belief that, even in a situation in which different divisions of the same company perform these two roles, there is an inherent conflict of interest. A company cannot make its living providing insurers with bases for denying coverage of a treatment or procedure while also remaining objective in appeals that may involve review of the same or related coverage policy. Again, as obvious as this may seem, we have encountered it twice already. The rules present a unique opportunity to address this issue clearly so that it needn't be litigated by individual consumers repeatedly.

Similarly, the rules should be clear that the internal review organization is chosen by the State, not by the issuer/plan. Some State laws, including, for example, Alaska and Utah, provide that managed care organizations must contract with the independent review organization(s). Alaska Stat. § 21.07.020; Utah Code Ann. § 31-22-629. To be sure to eliminate conflicts of interest, the selection of independent review organizations should be left to the States, not issuers or plans.

2. The rules provide that the State process must allow four months between the notice of adverse determination and the filing of the external appeal. 26 C.F.R. § 54.9815-2719T(c)(2)(vi), 29 C.F.R. § 2590.715-2719(c)(2)(vi), 45 C.F.R. § 147.136(c)(2)(vi). This is unusually long and most welcome. However, in the same breath, the rules require that the State allow the consumer at least five (5) business days to submit additional information to the IRO in writing. 26 C.F.R. § 54.9815-2719T(c)(2)(x), 29 C.F.R. § 2590.714-2719(c)(2)(x), 45 C.F.R. § 147.136(c)(2)(x). Although we have encountered this two-step process in some States, we see no reason for it, and we believe that it creates confusion. Typically, our preference is to submit the entire external appeal, including any new materials, simultaneously. With four months to file the external appeal, the rules provide consumers ample opportunity to submit all materials at once. If, instead, the filing of the external appeal does not include the filing of accompanying materials, five (5) days is a very short time in which to prepare supporting materials. At the very least, consumers should be advised in the notice of adverse determination that, if they do not submit everything they wish the IRO to review initially, they will only have five (5) days to file any additional materials they wish to submit. If they need to collect medical records or do additional research, five (5) days will not be long enough, so they should be on notice of this short deadline in advance.⁶

⁶ The Department of Labor has issued Interim Procedures for Federal External Review, Technical Release 2010-01. Those Procedures are too vague on the point of who will transmit the "claimant's" information to the IRO. Section 3(c) provides that the plan must provide the IRO any information it "considered" in rendering the adverse benefit determination, and section 3(b) states that the claimant

3. The rules provide that State external appeals should be conducted in a "substantially similar" manner to that found in the NAIC Model Act. 26 C.F.R. § 54.9815-2719T(c)(2)(xvi), 29 C.F.R. § 2590.715-2719(c)(2)(xvi), 45 C.F.R. § 147.136(c)(2)(xvi). We strongly urge the Agencies to be more specific to avoid needless litigation of what is considered "substantially similar."

In particular, the majority of external appeals that we file involve experimental or investigational determinations, and these cases almost always come down to a disagreement about whether the medical literature is sufficient upon which to base a finding that the treatment is not experimental or investigational. The standards to be used in such a case are especially important in cases involving relatively new treatments, or treatments of relatively rare diseases. The standard set forth in the NAIC Model Act is as follows:

[w]hether there is sufficient evidence to demonstrate that the recommended or requested health care service or treatment is more likely than not to be beneficial to the covered person than any available standard health care services or treatments and the adverse risks of the recommended or requested health care service or treatment would not be substantially increased over those of available standard health care services or treatments.

Section 10.H.2.b. Independent reviewers are directed to consider not only whether the recommended health care service is approved by the FDA, but, if it is not, whether "[m]edical or scientific evidence or evidence-based standards" demonstrate that the above standard is met. Section 10.I.5. The terms "medical or scientific evidence" and "evidence-based standards" are defined in the NAIC Model Act. Sections 3.DD, S.⁷

The use of a single standard such as this one by all States and the Federal external reviews would itself be a tremendously helpful consumer protection. Currently, each policy or plan has its own definition of "experimental or investigational," but typically, policies and summary plan descriptions do not provide guidance to either consumers or independent reviewers of the standard they must use to evaluate a treatment plan that the issuer/plan

may submit additional information to the IRO within ten (10) business days. It is unclear whether the plan must transmit to the IRO everything that it previously received from the claimant, including information that it did not rely on in reaching the adverse benefit determination, or whether the claimant must provide the IRO with all information it wishes the IRO to consider during that ten (10) day period. In addition, section 3(d) provides the plan with an opportunity to respond to any new information submitted by the claimant to the IRO; however, the same opportunity is not provided to the claimant. These omissions should be corrected.

⁷ The NAIC Model Act includes, *inter alia*, as "medical or scientific evidence," published medical journal articles or articles accepted for publication. However, it is extremely burdensome for consumers to have to obtain the full-text of medical journal articles since only abstracts are available without charge on the internet; one either has to go to a medical library (if one is nearby) or pay quite a high price for copies of full text articles on the internet. We suggest that the Agencies consider accepting, as "medical or scientific evidence," abstracts published on PubMed.gov or other similarly-reliable internet-based services. Vermont allows the use of peer-reviewed abstracts presented at major medical association meetings. Vt. Admin. Code §§ 4-5-3:10.100(11)(6)(managed care organizations); 4-5-4.3(S)(6)(health insurers). However, even these would be difficult for consumers to obtain. Thus, peer-reviewed abstracts from reliable sources such as PubMed.gov should be accepted.

deems to be experimental or investigational. The lack of clarity and uniformity mars the process. This is an issue that arises often enough – and, when it does, it often determines the result in the case – so that incorporating a uniform standard into the minimum consumer protections is desirable. Although we would support the use of the NAIC Model Act's standard, a uniform standard that sets forth the standards to use when the treatment is not FDA approved for the use for which it is prescribed, so that all stakeholders are on notice of the standard to be employed, should be included as a minimum consumer protection.

4. On the other hand, we urge the Agencies to eliminate one of the provisions of the NAIC Model Act that has, in our experience, constituted a roadblock to effective, timely resolution of external appeals from denials based on the assertion that a treatment is experimental or investigational. Any such case is initiated with a physician's order. Thus, requiring that the treating physician certify that standard treatments have not been effective, are not medically appropriate, or there is no standard treatment, and that the recommended treatment is likely to be more beneficial than standard treatments or there are scientifically valid studies demonstrating that the proposed treatment is likely to be more beneficial than standard treatments – all of that is redundant and, since not every physician is willing to assist with insurance appeals, it creates an unnecessary road block.

We recall a case in New York, which has a physician's certification requirement for experimental/investigational external appeals, in which the physician had lost the first level appeal and, after that, told the patient that he would not spend any more time fighting with the insurer on her behalf. We prepared the external appeal and sent the form to the physician for his signature. He was angry and the form sat on his desk for days despite daily telephone calls from both the consumer and the undersigned. Ultimately, he relented and signed the form before the filing deadline, but the experience taught us that this seemingly innocuous requirement can become a genuine obstacle to consumers seeking to pursue external appeals. There was no doubt that the physician had ordered the treatment and, thus, it was implicit that he felt that it was the best and most appropriate treatment available, and that he was utilizing his clinical skill and judgment in selecting the treatment in question. Therefore, the physician certification was redundant and unnecessary. We urge its elimination.

Some States require even more than the NAIC Model Act suggests. For example, Connecticut and New Hampshire require that the insured provide a copy of the certificate of coverage. Conn. Gen. Stat. § 38a-478n(c)(1)(B); New Hampshire Rev. Stat. Ann. § 420-J:5-b.VII.a. However, over and over, insurers have refused to provide us with a copy of the certificate of coverage. This sort of requirement should not be permitted. If the goal is to ensure that independent review organizations have a copy of the certificate of coverage or summary plan description, the burden of producing this document should be on the plan/issuer.

5. The consumer and/or his/her representative should be able to rely on the ground for coverage denial set forth in the notice of adverse decision. If an independent reviewer decides to uphold the denial for an entirely different reason than that on which the issuer/plan relied, the consumer and/or his/her representative should be given an opportunity to respond to this new rationale before a final notice of adverse decision is issued. The rules include this requirement for internal appeals, but not for external appeals.

26 C.F.R. § 54.9815-2719T(b)(2)(ii)(C)(2), 29 C.F.R. § 2590.715-2719(b)(2)(ii)(C)(2), 45 C.F.R. § 147.136(b)(2)(ii)(C)(2).

We recently had a case in which proton beam radiotherapy for treatment of a tumor called acoustic neuroma was denied on the ground that proton beam radiotherapy was deemed experimental/investigational. We filed several appeals and, eventually, an external appeal. The independent reviewer found that proton beam radiotherapy is not experimental/investigational for the treatment of acoustic neuroma, but that the plan's definition of "medically necessary and appropriate" included a finding that the therapy in question was more effective than other covered therapies. The external reviewer found that other therapies were equally effective and ruled against us on that ground. At no time had the issue of how proton beam radiotherapy compared to other therapies been raised by the plan, and we never had an opportunity to respond to this point.

This was not a one-time occurrence. Just this month, we filed several appeals from the denial of gastric electrical stimulation to a patient with idiopathic gastroparesis. There were four levels of appeal in all; the first three were denied based on the claim that gastric electrical stimulation is experimental/investigational. We updated our medical research and the medical records again before filing the final appeal, which consisted of approximately 1,000 pages of documents that overwhelmingly proved that gastric electrical stimulation is the standard of care for medically refractory idiopathic gastroparesis. The final decision we received rested on an entirely different rationale, i.e., that the patient's gastroparesis was caused by narcotic drug use due to chronic back pain, and was not idiopathic, thereby rendering the use off-label. We requested an opportunity to respond; in fact, our medical expert was prepared to state unequivocally that it is entirely unknown whether narcotic drug use can cause gastroparesis, and that, in this particular case, his best medical judgment is that the patient's past use of pain medication was not the cause of her gastroparesis. We received no response to this request. Today, this patient is on a feeding tube, in the hospital; her kidneys are shutting down; and her life hangs in the balance. To pursue coverage further, a case will have to be litigated in federal court – something that cannot be accomplished quickly enough to save the life of this consumer.

If an independent review organization is going to render a decision based on a rationale that never was raised before, the consumer must be given an opportunity to present his/her response to that rationale before a final adverse determination is issued.⁸

6. The Agencies have asked expressly whether the Federal external review process should apply when the State external review process does not apply to all issuers in the State. For example, some States have external appeal rules that apply only to HMOs. While we agree that it would be best if the States would broaden their procedures to apply to all issuers in the State, it seems to us that there can be no question that, in the absence of State external appeal, the Federal external review should be available.

7. We very much agree with the NAIC Model Act that the independent medical reviewers presiding over a case involving a denial of coverage as experimental or investigational should be "experts in the treatment of the covered person's condition and

⁸ This same point should be made in the context of DOL Technical Release 2010-01 at section 3(g). If the IRO bases its decision on entirely new grounds not previously raised by the plan, the claimant should have an opportunity to respond to that new ground.

knowledgeable about the recommended or requested health care service or treatment.”
Section 10.D.4.a. It is commonplace for issuers and plans to have medical reviews conducted by physicians and other health care professionals with no expertise or clinical experience in the field of medicine implicated by the appeal. We recommend that this provision be added to the list of minimum consumer protections required for a State external review process to be deemed sufficient by the Secretary.

8. The NAIC Model Act states that independent review organizations are not bound by any decision or conclusions reached during the health carrier’s utilization review process. Section 8.D.2. However, the interim final rule does not state whether the Federal external review will be *de novo*, as well. For an external review process to have teeth and genuinely be independent, there cannot be a deferential standard of review. We, thus, submit that Federal external appeal guidelines should track the NAIC Model Act on this point.

Conclusion

In our view, the appeal provisions set forth in Section 2719 of the Patient Protection and Affordable Care Act are among the most important consumer protections set forth in the Act. The expansion of external appeals to all non-grandfathered plans, including self-funded plans, will enable consumers to obtain all that their insurer is obligated to provide – nothing more, but also nothing less. The suggestions we have made herein would further that end. Thus, we hope that you will give them due consideration.

Thank you.

Sincerely,

A handwritten signature in black ink, appearing to read "Jennifer C. Jaff". The signature is fluid and cursive, with the first name being the most prominent.

Jennifer C. Jaff, Esq.
Executive Director