Claim Appeal Fiduciary Services, Inc.
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Re: Comments Submitted by *Claim Appeal Fiduciary Services, Inc*. Regarding the Interim Final Rules for Health Insurance Issuers Relating to Internal Claims and Appeals and External Review Processes Under the Patient Protection and Affordable Care Act, 75 F.R. 43330 (hereinafter referred to as the "PPA Claim Rules" or the "Rules")

Dear Ms. Turner, Ms. Baum, Ms. Kuhn and Ms. Levin:

On behalf of ***Claim Appeal Fiduciary Services, Inc.***, the undersigned respectfully submits these comments on the PPA Claim Rules (as defined in the reference above). We respectfully submit these comments primarily with respect to self-insured group health plans[1] that are subject to the Employee Retirement Income Security Act of 1974, as amended ("ERISA"). We urge full consideration of these comments, because the Rules can be greatly improved to more closely match the diverse range of self-insured, employer sponsored group

[1] The term "group health plan" used herein, has the same meaning as stated in the Rules at 75 F.R. 43331 at footnote No. 1.

health plans, if certain features of the Rules are augmented as described herein. If not, significant confusion, burden, and operational mismatches will result, increasing cost and reducing the effectiveness of the Rules.

With respect to these comments, in Part I, we provide an Executive Summary the main legal, operational and related considerations that we respectfully submit for consideration. In Part II, we provide some detail and background on Claim Appeal Fiduciary Services, Inc. and its principal, to establish our company's deep background and experience with ERISA-governed employee benefit plans, to give a point of reference to each of you, as representatives of the United States Department of Health and Human Services ("HHS"), The United States Department of Labor ("DOL") and the United States Department of Treasury ("IRS") (together HHS, DOL and IRS are referred to as the "Agencies")[2]. In Part III, we provide further explanation of the issues raised and proposed alternatives for consideration, with rationale.

I. Summary of Identified Problems with the Interim PPA Claim Rules.

A brief Executive Summary of our Comments on the Rules is as follows:

A. <u>The Federal External Review Process Fails to Consider That IROs Will Exercise Superceding Discretionary Authority And Become ERISA Fiduciaries.</u>

Under ERISA, any person or entity who exercises discretionary authority or control with respect to the management or administration of an ERISA-governed Plan, including the approval or denial of a final claim appeal, is an ERISA fiduciary, and liable as such.[3] This liability goes to the participants and beneficiaries and to the Plan itself and other fiduciaries. The Rules do not take this into account. Without an intervening third party or a Plan fiduciary in control of the External Review process, with discretion to evaluate and approve the work of any Independent Review Organization ("IRO"),[4] the IRO becomes and ERISA fiduciary of the plan and has the duty, responsibility and liability as such. This will result in numerous consequences. First, the IRO itself, and the individual medical professional rendering a decision who will become the ERISA fiduciary by operation of law, must become familiar with the standards that apply to ERISA fiduciaries. Second, there will be increased litigation risk and increased cost for IROs. Finally, this concept is inconsistent with Section 14 of the NAIC Model Act[5], which proposes to hold IROs harmless.

The solution lies in retention of control by Plan fiduciaries, or the use of any independent third party to manage the external review. This can include the use of an IRO, but the structure must consider the use of independent final claim appeal managers, or fiduciaries to take into

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[2] Respectfully, for purposes of group health plan issues raised herein, all references cited will be to the regulations issued by the DOL under Title 29 of the United States Code of Federal Regulations.

[3] ERISA 3(21)(A); 29 U.S.C. 1002 (21)(A).

[4] 29 C.F.R. 2590.715-2719(a)(2)(vii); 75 F.R. 43355.

[5] The National Association of Insurance Commissioners Uniform Health Carrier External Review Model Act referred to at 29 C.F.R. 2590.715-2719(a)(2)(viii), is referred to herein as the "NAIC Model Act."

account this ERISA created liability and tension. This is explained further below and will conform more closely to the NAIC Model Act, as required by the statute.

B. **The External Review Process As Proposed Does Not Conform to the NAIC Model Act and May Not "Consist Of" The NAIC Model Act**.[6]

Although the Rule states that the external review process will be "similar' to that of the NAIC Model Act, the Model Act addresses only denials based upon ***medical necessity and related causes***. It does not address denials based upon plan term violations (contract violations) or procedural violations. As such, this proposed Rule is not sufficient for this purpose with respect to group health plans. Moreover, as detailed in Technical Release 2010-1, it appears that the IROs will be called upon to broaden the scope of their reviews to considerations outside those "Adverse Determinations" as defined in the Model Act. This is contrary to the statute and the focus of the Model Act. Indeed, a process that is full and fair and EXTERNAL in scope can involve a third party, unaffiliated reviewer, that employs an IRO for medical necessity and related assessments based upon "Adverse Determinations" as contemplated by the NAIC Model Act, as part of a comprehensive External Review Process. But, to rely too much upon the NAIC Model Act, as the exclusive method of external review, will result in physicians and other similar health care providers becoming ERISA plan administrators, deciding and interpreting plan contract terms and procedural issues, which is simply not acceptable to such plans, and is impractical and a mismatch with operational reality.

A **critical error** being contemplated by those responsible for the Rules is stated in the most recent guidance. U.S. Department of Labor Technical Release 2010-1, dated August 23, 2010, requires that the IRO "utilize legal experts where appropriate to make coverage determinations under the plan." [7] This involves not only the potential of the unauthorized practice of law with respect to a plan, whereby the IRO becomes a legal advisor to a plan, which is contrary to rules of state regulation of attorneys, but otherwise means increased cost of use of IRO, potential conflict of interest for the legal advisors, or the need for every IRO to retain in house counsel – an added cost. Taking the existing named fiduciary out of the process goes beyond the scope of the statute and create the problems enumerated herein.

A solution lies in the retention of fiduciary control, a presumption that the IRO review is valid, and a process and alternative use of independent review or independent fiduciary concerns to process these External claims.

[6] See footnote 5 above for reference.
[7] U.S. Department of Labor Technical Release 2010-1, August 23, 2010, Section A(3)(a).

C. **The Proposed Rule Does Not Consider Professional Independent Review or Independent Fiduciary Roles With Respect to Final Claim Appeal Administration.**

ERISA and the goals and objectives of the Rule may be augmented by ensuring that an independent decision-maker, not subordinate to, not the same as, and not beholden to the prior decision-maker, undertake all aspects of the final appeal and any final External Review Process. This would be consistent with current regulations under 29 C.F.R §2560-503-1(h)(3)(ii).[8] By employing ***Principals of Independence*** to aid Plan fiduciaries and claimants in resolving denied claims in a productive manner, a Rule structure that encourages and promotes independent evaluations on ALL final claim appeals – internal and external, by claim and ERISA experts, with a structure that promotes and gives advantages to group health plan sponsors who employ qualified third parties that operate with ***Principals of Independence***, will result in full and fair review of claims at all levels. This process must, by statute, include the IRO process, but cannot consist of just IROs. There is no way an IRO selected on a rotating basis could provde the required fiduciary service or expertise. Thus, the under the Rules, group health plans should be encouraged to employ a fully functioning independent process either through independent review or independent fiduciaries for all final appeals, both internal and external final appeals to ensure quality, consistency and fairness.

A cost and time saving alternative exists. For the final claim appeal, under 29 C.F.R. §2560.503-1(h), in the event that a group health plan retains an independent fiduciary that: i) is not the same entity that provided the initial decision or first level review; ii) is not subordinate to the entity that made the initial decision or first level review; iii) has no pecuniary interest in the outcome of an appeal; and iv) employs three (3) IRO entities to handle any claim that includes an "adverse determination," as that term is defined under the NAIC Model Act, the Rules should deem such a procedure to be an external review that satisfies the requirements of the rule. This will reduce cost, reduce time and be more efficient, while preserving the use of rotating IROs, and preserve the independence sought by the rules.

D. **The Process Does Not Integrate With the Timing in Existing Regulations.**

The timing considerations of the new internal and external appeal process are not coordinated with the existing regulations at 29 C.F.R. §2560.503-1. They do not recognize that additional consultations and interactions with claimants will extend the time for resolving claims. The Rules do not provide firm response times for claimant review of new information. The rules place too high a burden on processors to be "perfect" without considering human error that may have no impact whatsoever on the decision-making process. Thus, they are not well integrated

[8] Group health plans are currently required to provide "for a review that does not afford deference to the initial adverse benefit determination and that is conducted by an appropriate named fiduciary of the plan who is neither the individual who made the adverse benefit determination that is the subject of the appeal, nor the subordinate of such individual. CAFS notes that often the appeal decision-maker is either the same entity, but a different department, which violates this rule because one entity cannot "not" be subordinate to itself. **The answer is easy. Plans should employ a different final claim appeal fiduciary for appeals.**

with the existing claim appeal structure, will inevitably involve longer appeal times and are unrealistic operationally. See also the alternative stated in Section C above, and discussed further below.

E. **The Rules Do Not Provide Enough Time for Plans to Adjust and Amend.**

The Rules do not give group health plans enough time to evaluate their alternatives, select an independent third party, and select an IRO that is accredited, pursuant to the Rules. Thus, plan sponsors and fiduciaries are left with insufficient time to implement internal or external final claim appeal review procedures to comply with the Rules. Indeed, it is unclear whether the existing accredited IROs have sufficient time and capacity to handle the additional External Appeal load. Additional time should be allowed.

II. Our Company – A Description

Claim Appeal Fiduciary Services, Inc. is an independent processor and/or independent fiduciary for final claim appeals for any type of employee benefit plan final claim appeal. Uniquely situated, and perhaps the only company of its kind in the nation, CAFS handles as an independent reviewer, or independent fiduciary, any type of employee benefit appeal. CAFS is expert in ERISA, fiduciary process, independent final claim appeal adjudication, and judicial process of claims. Staffed principally by persons with juris doctor degrees (JD), "CAFS" is the premier provider of independent final claim appeal processing and final claim appeal fiduciary services for employee benefit plans. Founded in its current form in 2004, CAFS serves large Fortune 500 Employer medical, disability, pension and other related employee benefit plans.

Our Chair and President, is an ERISA attorney who has been involved in ERISA for almost **twenty-five (25) years** and has advised plan officials, fiduciaries and has litigated ERISA disputes. Employing this deep experience in ERISA, plan structure, governance, fiduciary rules and operational understanding, CAFS' professionals serve large sophisticated employers as a final claim appeal processor, or independent fiduciary. Utilizing its ***10 Principals of Independence*** and with its intricate knowledge of claims process, ERISA, benefit plan structures and operations, CAFS and its professionals provide the highest level of independent final claim appeal processing. As a result, CAFS is the premier provider of independent final claim appeal services for employee benefit plans in the United States. This results in only advantages for CAFS clients, who can rely upon CAFS for sophisticated, high level, professional processing of final claim appeals for any type of employee benefit plan.

III. Considerations and Examples, Suggestions for Improvement – Self-Insured Plans

In this section, we endeavor to provide more detail on the specific points and comments that we deliver. We strive to be focused in our presentation of the issues and the manner in which the regulations can be improved.

A. **<u>The Federal External Appeal Process Makes IROs ERISA Fiduciaries</u>**.

ERISA Section 3(21) provides that:

> a person is a fiduciary with respect to a plan to the extent (i) ***he exercises any discretionary authority or discretionary control respecting management of such plan or exercises any authority or control respecting management or disposition of its assets***, (ii) he renders investment advice for a fee or other compensation, direct or indirect, with respect to any moneys or other property of such plan, or has any authority or responsibility to do so, or (iii***) he has any discretionary authority or discretionary responsibility in the administration of such plan***. Such term includes any person designated under section 405(c)(1)(B).

ERISA Section 3(21)(A); 29 U.S.C. § 1002(21)(A)(emphasis added).

Thus, "any person or entity who exercises discretionary authority or control with respect to the management or administration of an ERISA-governed Plan" is an ERISA fiduciary. According to the proposed federal external review procedure, an IRO will be retained to make the determination as to whether an "adverse determination" was valid and if the IRO overrules the prior decision-maker, the benefit is payable. Pursuant to NAIC Model Act Section 8, Subpart I, subparagraph 3, and the Rules at 29 C.F.R. §2590.715-2917(d)(2)(iv), upon receipt of a notice of a decision reversing the adverse determination, there is an automatic approval of the claim. Therefore, the person or entity performing the external review will decide whether a plan will or will not pay a benefit. Without some statutory modification to ERISA Section 404, the IRO and possibly the reviewer him or herself, is the person or entity with authority and control to manage the ERISA group health plan and thus, the ERISA fiduciary.

In sum, the IRO, or the individual medical professional working for the IRO making the approval or denial decision is an ERISA fiduciary.

An ERISA fiduciary must act in accordance with ERISA 404, which provides that:

> a fiduciary shall discharge his duties with respect to a plan solely in the interest of the participants and beneficiaries and—
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> (A) for the exclusive purpose of: (i) providing benefits to participants and their beneficiaries; and (ii) defraying reasonable expenses of administering the plan;
> (B) with the care, skill, prudence, and diligence under the circumstances then prevailing that a prudent man acting in a like capacity and familiar with such matters would use in the conduct of an enterprise of a like character and with like aims;
> (C) by diversifying the investments of the plan so as to minimize the risk of large losses, unless under the circumstances it is clearly prudent not to do so; and

> (D) in accordance with the documents and instruments governing the plan insofar as such documents and instruments are consistent with the provisions of this title and title I

ERISA Section 404(a); 29 U.S.C. § 1104(a)

An ERISA Fiduciary must perform up to its required fiduciary standards and is liable to participants, beneficiaries and other fiduciaries for breach of duty. Liability includes:

- Restore Any Losses to a Plan;
- Restore Any Profits Gained;
- Equitable Relief, including removal of fiduciary and all other available relief;
- 20% Civil Penalty;
- Prohibited Transaction Excise Tax;
- Criminal Penalties if Intentional Violation.[9]

For the IRO to become the ERISA fiduciary, and incur the obligations and exposure, will resulting increased cost, risk and operational difficulties. Since the IRO is selected on a rotating basis from at least three (3) providers under Technical Release 2010-1[10], it would be improbably for such an IRO to gain the requisite understanding of each particular plan that it serves. Without that understanding, the exercise of this duty is exceptionally difficult. Moreover, many IROs may decline this role, or leave this aspect of the business. Ultimately, this result is inconsistent the NAIC Model Act itself. Pursuant to Section 14 of the NAIC Model Act, the IRO is to be held harmless. Thus, the approach is a mismatch with ERISA and operational reality.

Proposed Solution to Fiduciary Impact of Use of IRO:

The solution lies in retention of ultimate control by Plan fiduciaries with a presumption in favor of the recommendation of the IRO. The use of an independent third party that is not the same entity, or subordinate to the entity that handed the initial and first level appeals is critical. That independent party or independent fiduciary would also manage the External Review, again, with a presumption that the IRO's recommendation should prevail. As provided in the statute, the External Review process must include the use of an IRO in instances where an "adverse

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[9] See ERISA Section 409, 29 U.S.C. §1109, ERISA 502(a)(3); 29 U.S.C. §1132(a)(3); ERISA Section 502(l), 29 U.S.C. §1132(l); IRC Section 4975, ERISA Section 501; 29 U.S.C.§1131.

[10] See footnote 7 above, at Section (A)(3).

determination" as defined by the NAIC Model Act is involved, but the structure must include the plan fiduciary. Otherwise, there is significant liability and tension created under ERISA.

Proposed Language - 29 C.F.R. §2590.715-2719(d)(2)(iv) would be replaced with the following new section (d)(iv) to read as follows:

> ***(d)(iv) These standards will provide for a presumption that an external review decision by an IRO is correct, and the group health plan fiduciary or independent fiduciary and the claimant, will adhere to the external review decision. In a circumstance where a group health plan has retained an independent fiduciary that: i) is not the same entity that provided the initial decision or first level review; ii) is not subordinate to the entity that made the initial decision or first level review; and iii) and has no pecuniary interest in the outcome of an appeal, such independent fiduciary to a group health plan may provide a process to overcome the presumption of correctness of an external review decision by an IRO, but only in the event of clear and convincing evidence that an IRO made a material error or omission of fact.***

B. <u>The External Review Process Cannot "Consist Of" the NAIC Model Act</u>.[11]

The use of the NAIC Model Act as the sole guidepost is simply inadequate to provide a proper, full and fair, final claim appeal external review for the various claim issues faced by self-insured group health plans on final appeal. The premise of the Rule is that the external final claim appeal review be "similar to the process set forth in the NAIC Uniform Model Act and will meet standards issued by the Secretary." 75 F.R. 43357.

The statutory authority specifically requires group health plans to "provide an external review process for such plans and issuers that, at a minimum, includes the consumer protections set forth in the Uniform External Review Model Act promulgated by the National Association of Insurance Commissioners and is binding on such plans." [12] Nowhere in the law does it specify, or even recommend that an external appeal consist solely of the NAIC Model Act. Nowhere in the law does it state that plan fiduciaries cannot obtain external review consideration from multiple sources of independent third parties. The law requires that group health plans **include** the protections in the Model Act, not consist of it.

As proposed, even though the regulations advise that the "Department will address in sub regulatory guidance how non-grandfathered self-insured group health plans that currently maintain an internal appeals process… may comply… with the requirements…."[13] The direction

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[11] See footnote 5, *infra for the reference to the definition of the* "NAIC Model Act."
[12] Public Health Services Act, Section 2719.
[13] 29 C.F.R. 2590.715-2719(d)(1) at 75 FR 43337.

indicated by the Rule, shows that the "Department" has significant considerations that must be undertaken.

A **critical error** being contemplated by those responsible for the rules is stated in the most recent guidance. U.S. Department of Labor Technical Release 2010-1, dated August 23, 2010, requires that the IRO "utilize legal experts where appropriate to make coverage determinations under the plan." [14] This involves not only the potential of the unauthorized practice of law with respect to a plan, whereby the IRO becomes a legal advisor to a plan, which is contrary to rules on state regulation of attorneys, but otherwise means increased cost of use of IRO, potential conflict of interest for the legal advisors, or the need for every IRO to retain in house counsel – an added cost.

Major issues presented by the initially proposed structure, with specific examples are as follows:

1. Adverse Determination Under NAIC Model Act is Limited in Scope.

Under the NAIC Model Act, the adverse determinations that are considered subject to and processed for external review is narrowly limited to claims denied based upon:

"medical necessity, appropriateness, health care setting, level of care or effectiveness."

NAIC Model Act Section 3, Definitions, part A.

Incongruently, the Rules recognize that adverse benefit determinations may be based upon a broader set of circumstances. Specifically, the Rules recognize that denial of benefits may be based upon:

- a determination of an individual's eligibility to participate in the Plan or health insurance coverage;
- a determination when the benefit is not a covered benefit;
- the imposition of a pre-existing condition exclusion, source of injury exclusion, network exclusion or other limitation or otherwise covered benefits; or
- a determination that a benefit is experimental, investigational or not medically necessary or appropriate.

In addition to those factors highlighted by the rules, there are ***other*** factors upon which adverse determinations are based that are ***also*** not included and considered with respect to the NAIC Model Act. These include:

[14] U.S. Department of Labor Technical Release 2010-1, August 23, 2010, Section A(3)(a).

- ► a determination that a required procedure or process requirement under a plan was not followed.

- ► a determination that information required to determine the validity of a claim has not been provided as required.

- ► a determination that an internal protocol or medical guideline requires the imposition of a certain course of treatment .

The obvious conclusion is that the NAIC Model Act, does not provide a process for the full and fair adjudication of the diverse range of determinations with respect to group health plans.[15] Specific examples of decisions outside and inside the scope of the Model Act are as follows:

Example 1 – A Sleep Apnea Dental Device - External Review? Claimant requests coverage for a dental appliance that is designed to assist the claimant with a sleep apnea condition. Medical necessity for the appliance is established and acknowledged in the form of a letter from claimant's primary physician. The Plan terms generally exclude dental procedures and devices from coverage unless as the result of accidental injury. Clearly, this fact pattern could result in an adverse determination that is wholly outside the scope of "adverse determination" as defined by the NAIC Model Act. A truly independent third party processor would, on external review, would review the administrative record, evaluate the plan terms, consult with plan administrators and make a valid final determination. This is outside the scope of a medical necessity assessment by an IRO, because it deals specifically with whether the group health plan covers such a device that has been medically cleared as necessary and appropriate. This decision involves plan terms and interpretation, not medical terms and medical interpretation. Thus, this decision should be solely within the purview of the plan fiduciary, or even better, an independent plan fiduciary.

Plan fiduciaries, or independent fiduciaries or reviewer experts should process these decisions. Such non medical plan decisions should not be made by IRO physicians or medical professionals.

Example 2 – Proton Pump Inhibitor or Not? Claimant files for coverage of a specified PPI drug designed to reduce acid reflux and stomach problems. In general, a PPI medicine has been approved as medically necessary by the claimant's primary physician. The specific PPI requested is specifically excluded from coverage under the plan, unless certain other PPI drugs are first attempted. The claimant's other use of NAISD anti-inflammatory drugs categorizes this claimant for certain types of preferred PPI drugs first. The main issue is the application and coverage of this guideline with respect to the condition of the claimant. This issue falls as to whether the drug prescribed and the coverage guidelines are "appropriate," as that term is

[15] The federal external review requirement under the Rule does recognize that eligibility determinations are outside the scope of the NAIC Model Act and federal external review, but there are more circumstances than not, that do not apply to the NAIC Model Act. 75 FR 43375.

referenced in the definition of "Adverse Determination" under the Model Act. It is likely that this issue would be a narrow issue to be addressed by the IRO. This is an instance where there ia a medical appropriateness issue to be addressed and processed by the IRO. If, however, the issue was payment of a co-payment or deductible, there would be no need for an IRO to evaluate this claim.

Example 3 – To Provide the Information Requested or Not? Claimant is eager to obtain approval for a medical treatment that would be covered by the group health plan. Prior to approval, the group health plan requires certain information from the claimants treating primary care physician and surgeon. The Claimant continuously fails and refuses to provide the required consents and coordinate the acquisition of the information from these medical professionals. Coverage of the requested medical service has nothing to do with medical necessity or the like, it is a procedural requirement under the group health plan. Any denial here would be based upon adherence to plan requirements that the claimant provide requested information, not an "adverse determination" as defined under the Model Act.

In sum, CAFS provides suggested additional methodologies for External appeal review that will involve and cover these circumstances, while adhering to the principals of full and fair review, independence, efficiency and integrity.

2. Determination of Approved IRO Under Model Act is Inconsistent With Group Health Plan National Operations.

Since there are multiple bases for adverse determinations that go beyond the scope of the medical necessity range provided for in the NAIC Model Act, Section 3A, if group health plans are required to employ NAIC approved IROs to process external claim appeals, the result will be that physicians will become plan administrators and determine process and plan contract term defects and the like.

For group health plans, this is inappropriate, contrary to solid fiduciary practices and illogical. Our proposed solution, includes the requirement of consideration of the NAIC Model Act, while preserving the integrity of plan processing for all concerned. See below.

3. Qualifications of IROs Is Too Narrow and Fails to Consider Third Parties That Serve Exclusively Group Health Plans Subject to ERISA on Broader Ranges of Topic.

There is no difficulty employing an IRO to perform the functions of an independent reviewer of a specific adverse determination based upon a factor enumerated within the NAIC Model Act, but beyond that, the Agencies should consider the use of independent third party final claim appeal managers, or final claim appeal fiduciaries to manage the entire process on an independent basis. Such independent fiduciary or independent claim reviewer should manage all such external reviews. IROs are included when an "adverse determination" arises, as defined under the Model Act, and otherwise, may handle such final claim.

Proposed Solution:

To avoid the over use and inappropriate use of IROs on external review, the Rules should track the definition of "Adverse Determination" and require the use of an IRO only in the event of a determination related to "an admission, availability of care, continued stay or other health care service that is a covered benefit [that] has been reviewed and, based upon the information provided, does not meet the [plan's]… requirements for medical necessity, appropriateness, health care setting, level of care or effectiveness…." and where the claim was denied on that basis. Indeed, the plan fiduciary or reviewing coordinator can manage the external reviews much better if the precise standard of the Model Act is applied. See NAIC Model Act, Section 3(A).

The preliminary review phase of a request for an External Federal Appeal, should include a filter, by the plan fiduciary that calls for the use of an IRO for this review in such instances. Any other instances, are not suitable for external review, or should be handled under perhaps a voluntary review that involves another type of third party independent, like CAFS. utilization review, availability of care, continued stay or other health care service that is a covered benefit does not meet medical necessity. Any other issues, should be left to the Plan fiduciary.

See also, the proposed solution stated in Section C below.

C. **The Process Does Not Fully Consider Factors that Create Independence.**

ERISA and the goals and objectives of the Rule may be augmented by ensuring that an independent decision-maker, not subordinate to, not the same as, and not beholden to the prior decision-maker, undertake all aspects of the final appeal and any final External Review Process. By employing ***Principals of Independence*** to aid Plan fiduciaries and claimants in resolving denied claims in a productive manner, a Rule structure that encourages and promotes independent evaluations on all final claim appeals – internal and external, by claim and ERISA experts, with a structure that promotes and gives advantages to group health plan sponsors who employ qualified third parties that operate with ***Principals of Independence***, will result in full and fair review of claims at all levels. This process can include the IRO process, but group health plans should be encouraged to employ a fully functioning independent process for all internal and external final appeals to ensure quality, consistency and fairness.

Proposed Solution to Improve Independent Review:

The Rule should encourage the use of an independent fiduciary, or independent reviewer expert that is retained by the plan. This independent should adhere to certain principals of independence and importantly, not be subordinate and not be the same entity that provided the initial and first level appeal and have no pecuniary interest in the outcome of the decision. The use of such an independent review or independent fiduciary, should be encouraged with a presumption that such decision, unless erroneous by clear and convincing evidence, is correct.

Proposed Rule: In the event that a final review claim appeal is handled by an independent fiduciary that employs an IRO as appropriate, and consistent with the Model Act, the Rules should deem the federal external claim appeal process as having been satisfied at the final review stage. This will permit the reduction in overall time and effort, preserve cost, and preserve fiduciary integrity of final claim appeal processing.

A new section, 29 C.F.R. §2590.715-2719(d)(2)(viii) would be added to read as follows:

> ***(d)(viii) In the event that in the final claim appeal review under 29 C.F.R. §2560.501-1(h), the group health plan employs an independent fiduciary, that: i) is not the same entity that provided the initial decision or first level review; ii) is not subordinate to the entity that made the initial decision or first level review; iii) has no pecuniary interest in the outcome of an appeal; and iv) employs the use of one of three (3) IROs on a rotating basis to handle any "adverse determination", as that term is defined in the NAIC Model Act, then the federal external review process is deemed satisfied.***

D. <u>The Process Does Not Integrate With the Timing in Existing Regulations.</u>

The Agencies should consider fully the impact on claim appeal timing presented by the Rules. Below is a chart exemplar of the impact of a federal external review on a standard post service non-emergency appeal, as follows:

Event	Old Timeline	New Timeline
Initial Claim	Day 1	Day 1
Initial Denial	Day 30	Day 30
Claimant Considers Denial And Files First Level Internal Appeal	Day 60	Day 60
First Level Appeal Denied Within 30 Days	Day 90	Day 90
Claimant Files Final Internal Appeal Promptly	Day 100	Day 100
Plan Obtains Additional Information on Final Appeal at Day 110 (20	Day 110	Day 110

Days Remain)		
Plan Sends Information to Claimant for Consideration and Tolls file 30 days	N/A	Day 140
Comment from claimant – received on 30th day	N/A	Day 170
Plan Denies Final Internal Appeal	Day 140	Day 190
External Review Filing (up to 120 days)	N/A	Day 310
Preliminary Review and Notice and Assignment to IRO	N/A	Day 316
IRO Issues Decision within 45 Days	N/A	Day 361
Total Days to Process – Assuming no tolling and assuming all business days	**140**	**361**

This Chart demonstrates clearly, that the impact of the additional considerations under the Rules, while admirable, will no doubt create additional delay, unless there is a management process in place. This either requires reasonable time mandates upon claimants to respond to inquiries, or the potential of altering the process to permit external reviews to be undertaken earlier in the process. Otherwise, there will be a delay in processing final claims to decision under the Rules. See the proposal under Section C, for a method of adhering to the statutory requirement and shortening the time frame, by incorporating the external review as part of the final appeal process under 29 C.F.R. §2560.503-1(h).

E. **The Rules Do Not Provide Enough Time for Plans to Adjust and Amend.**

The Rules are effective with respect to group health plans for plan years beginning on or after September 23, 2010. For most group health plans, this means an effective date of January 1, 2011. It also means that the plans must be modified much sooner than that.

The Agencies must understand that group health plans offer open enrollment, months in advance of a new plan year. These open enrollment periods permit plan sponsors and fiduciaries to communicate to participants and beneficiaries the new terms and conditions of coverage and options. This means that for many, beginning October 1, 2010, plans will need to be able to communicate regarding updated procedures, that will take effect January 1, 2011. The Rules, with respect to non-grandfathered plans that require a federal external review, have not been completely provided and are subject to sub-regulation advisory from the Agencies. In addition, fiduciaries of plans must select a process for obtaining IRO review that meets the fiduciary standards of ERISA and plan needs.

In order for this to work reasonably, it is essential that plans be given more time to implement. Thus, the Agencies should extend the application of the Rules to nongrandfathered plans for one year, to plan years beginning after December 31, 2010.

Conclusion.

These comments to the Rules are respectfully submitted as of the date of this letter and we appreciate the Agency attention to them.

If there are any questions or comments regarding these submitted comments, please contact our President and CEO directly at jzimon@appealfiduciary.com or 216-789-8775.

Very truly yours,

CLAIM APPEAL FIDUCIARY
SERVICES, INC.

/s/ Claim Appeal Fiduciary Services, Inc.

Exhibit A

Ten (10) Principles of Independence

CAFS maintains its independence and avoids conflict of interest because:

1. CAFS does not have any primary economic interest in the funding of an employee benefit plan. It sustains only the ERISA fiduciary exposure under law.

2. Payment of CAFS' fees and expenses is made in advance of rendering any decision through advanced payment, or retainer or other similar arrangements.

3. Contract terms are longer, which gives CAFS freedom to perform independently.

4. CAFS has no interest in the profitability of any client, through the holding of equity in any clients, or otherwise.

5. CAFS does not accept any gifts or gratuities of material value.

6. There are no consequences to CAFS based upon the approval or denial of any claims.

7. Care and thought is undertaken in disclosures of information about CAFS to its clients, so that such information about CAFS can never be used to apply improper pressure.

8. CAFS has contractual access to senior management and/or independent board member decision-makers, to report any improper pressure or influence.

9. CAFS has full and free access to information and internal staff of its clients who may be needed to investigate facts and circumstances.

10. CAFS has full access to plan documents, and related policies and procedures and overall response time agreements in place with each client.