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Submitted Via Federal Rulemaking Portal: http://www.regulations.gov

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW.
Washington, DC 20201
Attn: CMS-9993-IFC2.

RE: Amendment to the Interim Final Rules for Group Health Plans and Health Insurance Relating to Internal Claims and Appeals and External Review Processes

To Whom It May Concern:

The U.S. Chamber of Commerce (the "Chamber") is submitting these comments in response to the Amendment to the Interim Final Rules for Group Health Plans and Health Insurance Relating to Internal Claims and Appeals and External Review Processes ("Amendment to the IFR" or "regulation"), which were published in the Federal Register on June 24, 2011.[1] The Amendment to the IFR provides guidance pursuant to the statutory language of the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act (collectively referred to as "PPACA").[2] As with other guidance under this Act, the Amendment to the IFR was published jointly by the Department of the Treasury, the Department of Labor and the Department of Health and Human Services (the "Departments").[3]

The Chamber is the world's largest business federation, representing the interests of more than three million businesses and organizations of every size, sector and region, with substantial membership in all 50 states. These comments have been developed with the input of member companies with an interest in improving the health care system.

[1] Group Health Plans and Health Insurance Issuers: Rules Relating to Internal Claims and Appeals and External Review Processes, 76 Fed. Reg. 37,208-34 (June 24, 2011) (to be codified at 26 C.F.R. pts. 54; 29 C.F.R. pt. 2590; 45 C.F.R. pt. 147) [hereinafter Amendment to the IFR].

[2] Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010), amended by Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, 124 Stat. 1029 (2010).

[3] Pursuant to the request in the Amendment to the IFR, the Chamber is submitting these comments to one of the Departments - The Department of Health and Human Services, with the understanding that these comments will be shared with the Department of Labor and the Department of Treasury as well.

OVERVIEW

The U.S. Chamber of Commerce and our member companies support providing employees and plan participants an opportunity to challenge adverse benefit claim determinations in a meaningful way without the need for litigation. We support the principle of guaranteeing individuals a fair and unbiased process for questioning significant plan determinations. Participants in ERISA-covered plans already have access to such a process. Such plans and their issuers must comply with internal claims and appeals requirements as stipulated by the Code of Federal Regulations.[4] Additionally, the majority of states have created external review requirements with which health insurers must comply.[5] The original Interim Final Rule (the "IFR") expanded on these requirements in several respects, some ill-considered. Although the Amendment to the IFR greatly improves it, several critical problems remain.

We appreciate the consideration of the Departments and their response, through this Amendment to the IFR, to the concerns the Chamber highlighted in our initial comment letter sent on September 21, 2010 in response to the original IFR.[6] The modifications made to the urgent care benefit determination notification provision will help advance the critical goals of protecting consumers while not imposing expensive and undue burdens on issuers. Despite slight revisions to other problematic requirements contained in the original IFR, we continue to have concerns with elements of the Amendment to the IFR as well as the timing.

The Chamber strongly recommends that the Departments provide an additional extension to allow good faith compliance until at least January 1, 2013 and that states be given until that date to pass laws and set up external review procedures in compliance with the NAIC Model. Although the Amendment to the IFR was issued in June 2011, these rules have been ever evolving since initially promulgated mid-2010. Realistically, plans can start to comply today, but given the significant changes, there are bound to be problems that will need to be ironed out. More time is needed.

Further, we continue to have concerns with the following elements of the Internal Claims and Appeals and External Review processes.

Internal Claims and Appeals Processes

1. To whom (and under what conditions) must plans and issuers send diagnostic and treatment codes and their corresponding meanings in order for a claim to be identified;

2. The definition of the de minimis exception to the strict compliance standards for the internal claims and appeals process;

3. The requirement to provide a written explanation of an alleged violation of the internal claims and appeals process;

[4] Final Rule on Claims Procedure, 65 Fed. Reg. 70, 246 -70271 (November 21, 2000) (codified at 29 C.F.R. pt. 2560).
[5] According to The Henry J. Kaiser Family Foundation, 44 states including the District of Columbia in 2008 had external review processes in place that plans were required to follow. (Available at: http://www.statehealthfacts.org/comparetable.jsp?cat=7&ind=361)
[6] U.S. Chamber of Commerce Comments to Interim Final Rules for Group Health Plans and Health Insurance Coverage Relating to the Internal Claims and Appeals and External Review Processes Under the Patient Protection and Affordable Care Act, 75 Fed. Reg. 43,330-64 (July 23, 2010) (to be codified at 26 C.F.R. pts. 54 and 602; 29 C.F.R. pt. 2590; 45 C.F.R. pt. 147).

4. The requirement to provide oral language services in order to satisfy the statutory requirement to provide notices in a culturally and linguistically appropriate manner;

External Review Process

1. The scope of the federal external review processes;

2. The possible fiduciary obligation conferred to an external reviewer when decisions made are binding; and

3. The mandate that external review be conducted de novo.

Although we appreciate the easing of several components of the original IFR, these elements continue to be very problematic. Not only are these requirements excessively burdensome and unnecessary in achieving the goal of protecting consumers, they will also drive up the costs associated with providing health care coverage.

INTERNAL CLAIMS AND APPEALS PROCESSES

1. Diagnostic and Treatment Codes

The Chamber raised several concerns regarding the original IFR's requirement to provide diagnostic and treatment codes as information sufficient to identify a claim. While one of our concerns, the administrative burden, difficulty and expense in providing this information has been addressed by the change in the Amendment to the IFR, our other concern regarding privacy remains. We believe that the Amendment to the IFR is much improved and that requiring plans and issuers to include a statement of the availability, upon request, of the diagnostic and treatment codes and their corresponding meaning and provide them to participants and beneficiaries only upon request is far less burdensome.[7] However, we believe additional clarification should be provided regarding to whom these codes and meanings must be provided and under what circumstances. For instance, should the individual for whom the claim relates have to give the plan permission to send the information to another individual? Should parents be permitted to request this information for a dependent child? Additional work remains to insure that this information is not shared without proper consent and to protect the privacy and medical information of individuals.

We recommend that the codes and their meanings should only be permitted to be provided to the affected covered participant or beneficiary, upon written request. If the covered individual is a minor, then the codes should be provided only to the participant/parent/guardian under whose plan the dependent beneficiary is covered. Further, proper written consent may be secured to provide these codes and their meanings to others.

2. De minimis exception

The Chamber appreciates the recognition that not all errors should permit enrollees to sidestep the internal review process. As reflected in our prior comments to the original IFR, a strict adherence requirement is improper, particularly given the extensive, detailed requirements. There are endless

[7] Amendment to the IFR, 76 Fed. Reg. at 37232 (June 24, 2011) (to be codified at 45 C.F.R. pts. 147.136(b)(2)(ii)(E).

possibilities for inadvertent and insignificant errors as plans attempt to follow the complex mandated internal review process, many of which would not harm the claimant and are unintentional.

Although the Departments seem to acknowledge in the Amendment to the IFR the need for a de minimis exception as we requested, they have drafted the de minimis exception so exceedingly narrowly that it will not in fact "except" de minimis errors. According to Merriam-Webster, de minimis is defined as "lacking significance or importance, so minor as to merit disregard," and synonymous with "negligible, inconsequential, inconsiderable, insignificant, nominal, trivial."[8] However, the de minimis exception stipulates that only it can only be applied when "the plan or issuer can demonstrate that the violation was for good cause or due to matters beyond the control of the plan or issuer."[9] The question remains: what about simple mistakes that are not likely to cause prejudice or harm to the claimant? Many simple and trivial mistakes that do not harm the claimant can still be said to be within the control of the plan. In order to allow this exception to ameliorate the concerns that strict adherence creates, the de minimis exception must be revised to exclude the phrase "so long as the plan or issuer demonstrates that the violation was for good cause or due to matters beyond the control of the plan or issuer."[10]

Secondly, the requirement that the purported violation must have occurred "in the context of an on-going good-faith exchange of information" should also be eliminated. It should be sufficient to excuse minor errors which are non-prejudicial, non-material and not reflective of a pattern or practice of noncompliance.

Finally, placing the burden on the plan or issuer to prove the violation meets the standard will not prevent participants from making an end run around the claims procedure as a practical matter. Participants will simply sue; they will allege material violations of the claims rule and the employer will not be able to force the case back on a motion to dismiss since there will be a factual issue of whether the exception applies. Once deeply into the litigation, courts are likely to be loathe to send cases back. It is more appropriate to place the burden on the participant to show (and plead) why he/she was materially prejudiced by the violation. To correct this problem, we recommend that the process be revised. Instead, if a participant believes that there is substantial noncompliance, a written notice should be provided to the plan administrator of the participant's belief that the plan has not been in substantial compliance with the regulations governing the internal review process and he/she has a right to go directly to the external review process or to court. Then the plan can respond that it believes it has been in full compliance or that there are sufficient reasons for the de minimis exception to apply. This would ensure that there is a record for later reviewers or the court to decide whether the claimant has a right to immediate review.

3. Written explanation of violation

The requirement to provide a written explanation of the violation within 10 days upon the claimant's request appears to be open-ended.[11] It does not contemplate situations where the violation has been corrected or any time limitations as to how long a claimant has to request an explanation. A plan or

[8] http://www.merriam-webster.com/dictionary/de%20minimis
[9] Amendment to the IFR, 76 Fed. Reg. at 37233 (June 24, 2011) (to be codified at 45 C.F.R. pts. 146.136(b)(2)(ii)(F)(2).
[10] Amendment to the IFR, 76 Fed. Ref. at 37233 (June 24, 2011) (to be codified at 45 C.F.R. pts. 147.136 (b)(2)(ii)(F)(2).
[11] Amendment to the IFR, 76 Fed. Reg. at 37233. (June 24, 2011) (to be codified at 45 C.F.R. pts. 147.136(b)(2)(ii)(F)(2).

issuer may need time to research and investigate the nature of the violation – particularly if it is regarding an older or complex claim. Therefore, we propose several recommendations:

1. Plans or issuers should only be required to provide this written explanation up until the time the violation is corrected.
2. Such an explanation should only be required to be provided for a claim or violation that occurred in the past 12 months;
3. The plan or issuer must be given up to 30 days to provide the written explanation.

Without including these caveats, requests for written explanation of violations are likely to further increase the cost of providing health care coverage and additionally impose unnecessary administrative burdens on plans and issuers.

4. Culturally and linguistically appropriate

While we appreciate the moderate improvements made to this requirement in the Amendment to the IFR, the requirement to offer oral language services is exceedingly burdensome and costly. Although the Departments include a cost discussion with regard to the requirement to provide notices under the applicable non-English language upon request under the Economic Impact and Executive Order Sections of the Preamble,[12] there is no such discussion about the cost of providing oral language services, which is likely to be exceedingly significant. We ask the Departments to conduct an economic analysis of the costs associated with providing oral language services so that a proper cost-benefit analysis can be conducted.

Previously, the IFR required a plan or issuer to provide oral language services in the non-English language only "to the extent the plans or issuer maintains a customer assistance process (such as a telephone hotline) that answers questions or provides assistance with filing claims and appeals."[13] Now, the Amendment to the IFR appears to require oral language services regardless of whether the plan or issues maintains a customer assistance process. "The Plan or issuer must provide oral language services (such as a telephone customer assistance hotline) that include answering questions in any applicable non-English language and providing assistance with filing claims and appeals (including external review) in any applicable non-English language."[14] For plans and issuers that do not currently offer a customer call center, it will be quiet costly and difficult to create one. We suggest that the departments re-insert the language from the original IFR so that plans and issuers are only required to provide oral language services to the extent that they maintain a customer assistance process.

Finally, we urge the Departments to allow sufficient lead time initially and annually before mandating plans to provide oral language services. Plans and issuers must be afforded the necessary time to hire, train and roll-out the provision of non-English oral language services.

[12] Amendment to the IFR, 76 Fed. Reg. at 37224-5.

[13] Group Health Plans and Health Insurance Relating to Internal Claims and Appeals and External Review Processes Under the Patient Protection and Affordable Care Act, 75 Fed. Reg. at 43,363 (July 23, 2010) (to be codified at 45 C.F.R. pts. 147.36 (e)(1)(ii)(C). [hereinafter IFR].

[14] Amendment to the IFR, 76 Fed. Reg. at 37234 (June 24, 2011) (to be codified at 45 C.F.R. pts. 147.136(e)(2)(i).

EXTERNAL REVIEW PROCESS

1. Scope of Federal external review

As the Chamber asserted in our prior comments in response to the original IFR, the scope of the federal review process should not include the review of questions involving plan design or law. While conceptually, we appreciate the revised scope of the external review process in the Amendment to the IFR and advocate that the suspension of the general rule be made permanent,[15] there are details as to its application with which we disagree.

We appreciate the statement in the preamble that "this amendment suspends the broad scope of claims that involve medical judgment (excluding those that involve only contractual or legal interpretation without any use of medical judgment), as determined by the external reviewer."[16] However, following this appropriate and correct statement of scope are several improper examples delineating what situations involve questions of medical judgment. The Chamber believes that several of these situations instead involve contractual and legal issues which are outside the scope of federal external review.

An adverse medical determinations based on the appropriate health care setting for providing medical care to an individual[17] is often a matter of plan design. For example, under previous guidance, with respect the preventive care, the agencies specified that it is within a plan or issuer discretion to determine the frequency, method, treatment or setting for preventive care where it is not otherwise specified. [18] Secondly, an adverse benefit determination based on whether a participant or beneficiary is entitled to a reasonable alternative standard for a reward under the plan's wellness program is similarly not a medical judgment.[19] This too is an issue that relates to the plan design and is a contractual, legal issue.

Additionally, as mentioned in our comments to the original IFR, not all rescissions should be considered an appealable adverse benefit determination.[20] As the Chamber previously discussed in comments filed in response to the "rescission" IFRs,[21] the IFRs improperly create an entitlement to

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[15] Amendment to the IFR, Fed. Reg. at 37233 (June 24, 2011)(to be codified at 45 C.F.R. 147.136 (d).

[16] Amendment to the IFR, Fed. Reg. at 37216 (June 24, 2011).

[17] Amendment to the IFR, Fed. Reg. at 37216 (June 24, 2011).

[18] Group Health Plans and Health Insurance Coverage Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act, 75 Fed. Reg. at 41,728-9 (July 19, 2010) (to be codified at 26 C.F.R. pt. 54; 29 C.F.R. pt. 2590; 45 C.F.R. pt. 147) "If a recommendation or guideline for a recommended preventive service does not specify the frequency, method, treatment or setting for the provision of that service, the plan or issuer can use reasonable medical management techniques to determine any coverage limitations."

[19] Amendment to the IFR, Fed. Reg, at 37216. (June 24, 2011)

[20] Internal Claims and Appeals and External Review Processes, 75 Fed. Reg. at 43,358 (to be codified at §147.136(a)(2)(i): "An adverse benefit determination means an adverse benefit determination as defined in 29 CFR 2560.503-1, as well as any rescission of coverage, as described in §147.128 (whether or not, in connection with the rescission, there is an adverse effect on any particular benefit at that time.)". Id, 75 Fed. Reg. at 43,359 (to be codified at §147.136(b)(2)(ii)(A): "an 'adverse benefit determination' includes an adverse benefit determination as defined in paragraph (a)(2)(i) of this section. Accordingly, in complying with 29 CFR 2560.503–1, as well as the other provisions of this paragraph (b)(2), a plan or issuer must treat a rescission of coverage (whether or not the rescission has an adverse effect on any particular benefit at that time) as an adverse benefit determination. (Rescissions of coverage are subject to the requirements of § 147.128 of this part.)"

[21] U.S. Chamber of Commerce Comments to Interim Final Rules for Group Health Plans and Health Insurance Coverage Regarding Preexisting Condition Exclusions, Lifetime and Annual Limits, Rescissions and Patient Protections under the Patient Protection and Affordable Care Act, 75 Fed. Reg. 37,188–37,241 (June 28, 2010) (to be codified at 26 C.F.R. pts. 54 & 602; 29 C.F.R. pt. 2590; 45 C.F.R. pts. 144, 146 and 147) [hereinafter Preexisting Condition Exclusion, et al]

mistakenly provided coverage or benefits. When the enrollee had neither a reasonable expectation of coverage, nor a right to coverage, under plan or contract terms or otherwise applicable law, it is wrong to treat the correction of that error as a "rescission." Hopefully, the agencies will correct the rescission IFR to make it clear that correcting such a coverage error is not a rescission. Therefore, a correction of this type should not be treated as an adverse benefit determination.

Finally, it should be the plan or issuer who decides whether something is within the scope of review. It is improper to delegate to the reviewer, the authority to decide whether the issue is a medical judgment and therefore within their authority to review.

2. Fiduciary obligation conferred to IRO

The Amendment to the IFR does not discuss the apparent ERISA fiduciary duties that IROs will be performing if their decisions are final and binding and subject only to review in court. Indeed, according to the Amendment to the IFR, plans must pay the claim if so directed by the IRO. Under applicable ERISA principles, the IROs are making decisions regarding payment of plan assets and are therefore ERISA fiduciaries. This is a critical issue that the IFR and now the Amendment to the IRF ignore. If an IRO makes an improper decision, the plan will experience a loss, and the IRO would appear to be liable if it breached any ERISA fiduciary duty. This Pandora box of issues needs full comment and vetting in standard regulatory proceedings.

3. De novo review

The Chamber requests that the Departments clarify when external review is to be conducted de novo. In reading the preamble discussion, it appears that de novo review should be used by an external reviewer when a plan fails to comply with the requisite internal claims and review processes. Given the Amendment to the IFR's creation of a de minimis exception, we interpret the preamble to mean that when a plan fails to follow the procedural requirements of internal claims and appeals process, the claimant may pursue external de novo review. However, if a plan's violation of the internal claims and appeals processes constitutes a de minimis exception, the claimant is not only required to continue through the internal claims and appeals process but he/she will also be subject to an external review which considers the findings of the prior reviewers – i.e. not de novo.

CONCLUSION

The U.S. Chamber of Commerce appreciates the Departments' on-going consideration of these rules and stakeholder comments. We look forward to assisting the Departments as they revise and improve these regulations to create workable and reasonable requirements for internal claims and appeals and external review processes, as intended by the statute.

Sincerely,

Randel K. Johnson
Senior Vice President,
Labor, Immigration, & Employee Benefits
U.S. Chamber of Commerce

Katie Mahoney
Director,
Health Care Regulations
U.S. Chamber of Commerce