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September 21, 2010

Comments submitted electronically via http://www.regulations.gov

Office of Consumer Information and Insurance Oversight
Department of Health and Human Services
Attention: OCIIO-9993-IFC
P.O. Box 8016
Baltimore, Maryland 21244-1850

Re: Interim Final Rules re: Appeals Process for Group Health Plans and Health Insurance Coverage in the Group and Individual Markets

File Code: OCIIO-9993-IFC

To Whom It May Concern:

The Center for Medicare Advocacy, Inc. (the Center) is a national, non-profit organization that advocates for fair access to Medicare and health care on behalf of older people and people with disabilities. We thank you for the opportunity to comment on the interim final rules (IFR) concerning appeals processes for group health plans and health insurance coverage in the group and individual markets under the Patient Protection and Affordable Care Act that were published in the Federal Register on July 23, 2010. 75 Fed. Reg. 43330-43364.

I. Overview

Our comments are based upon our extensive experience with helping beneficiaries navigate the Medicare appeals process, particularly appeals through private health insurance coverage (Medicare Advantage and Part D plans).

In general, we believe that these new rules provide for significant beneficiary protections, particularly with respect to information that plans and issuers must provide to beneficiaries when issuing an adverse benefit determination. In several instances, requirements of plan sponsors go beyond what is required in the Medicare Advantage and Part D contexts; many of these rules should serve as a model for further strengthening beneficiary protections in the Medicare arena.

Although we recognize that the following recommendation would require a legislative (rather than regulatory) fix, we believe that the scope of these rules should be applied to grandfathered plans as defined in section 1251 of the Affordable Care Act.

Our specific comments are set forth below.

II. Internal Claims & Appeals

We endorse each of the six new requirements of group health plans and health insurance issuers offering group health insurance coverage to those in the Department of Labor's claims procedure regulation, with further clarifications and suggested improvements outlined below (preamble, pp. 43332-43334). We also endorse the three additional requirements of health insurance issuers offering individual health insurance coverage, also with further clarifications below (p. 43334).

Definition of Adverse Benefit Determination Subject to Review

Interim Final Rule 45 CFR §147.136(a)(2)(i) refers to 29 CFR 2560.503-1 for a definition of adverse benefit determination, but adds that rescission of coverage is included in that definition. The preamble of the IFR articulates a broad range of issues included in such a definition, including both pre-service and post-service denials (p. 43332). Instead of referring to the DOL regulation and/or relying upon the preamble language to flesh out the full meaning of adverse benefit determination, for purposes of clarity, the final rule should include everything within the scope of that term.

Plan Deadlines

We applaud the change in the timeline within which plans must notify an individual with respect to a claim involving urgent care (to 24 hours down from 72) found at 45 CFR

§147.136(b)(3)(ii)(B). We believe this further strengthens beneficiary protections during health care crises.

While 29 CFR 2560.503-1(f) provides timeframes within which plans must issue decisions in urgent care and other claims, such as pre-service and post-service denials, the final rule should also clearly articulate these timeframes, and make clear that the number of days are counted in calendar days instead of business days. The issue of calendar versus business days has been an on-going problem in Medicare, where private plans have tried to weaken beneficiary protections and delay decisions by counting time in business rather than calendar days.

Information Upon Which Adverse Benefit Determination is Made

We strongly endorse the interim final rule's additional criteria to ensure that a claimant receives a full and fair review found at 45 CFR §147.136(b)(2)(ii)(C), as well as additional information required by notice under 45 CFR §147.136(b)(2)(ii)(E). The information that plans must provide to enrollees about the plan's decision-making will greatly enhance the ability to first understand the reasons for a denial, and second to mount an informed appeal of such denial.

In addition to a "description of the plan's or issuer's standard, if any, that was used in denying the claim" required by 45 CFR §147.136(b)(2)(ii)(E)(2), we recommend that any external standards upon which a plan bases its decision must also be made available and provided to an enrollee. Based upon our experience in the Medicare arena, often plans base coverage decisions on external, often proprietary information to which plan enrollees have no access. For example, in the Medicare hospital and home health settings, plans frequently use private company software or other mechanisms of analysis to determine whether a stay or visit will be covered (e.g., reliance upon standards and evaluation criteria developed by the private company Interqual). In addition, in the Medicare Part D arena, health plans and other decision-makers make determinations about acceptable and coverable off-label uses of particular drugs based upon one of several drug compendia, to which the public has no ready access. Information about these external sources upon which coverage decisions rely are just as important in mounting an effective appeal as plan internal standards.

Note that we provide additional comments regarding culturally and linguistically appropriate notice below.

Escalation to External Review

Overall, we are supportive of the enrollee rights outlined in 45 CFR §147.136(b)(2)(ii)(F) with respect to deemed exhaustion of internal claims and appeals processes. Instead of just allowing a claimant to initiate an external review in the case of a plan or issuer that

fails to strictly adhere to all applicable requirements, we assert that in such instances a claim should be automatically escalated to external review. When a plan fails to meet its obligations to an enrollee, the burden of plan non-compliance should not be shifted to the enrollee; in other words, the onus should not be on an individual to seek redress if a plan fails to adhere to appeal requirements outside of determining the merit of the claim at issue. We note that in the Medicare Advantage context, a plan's failure to comply with appeal deadlines automatically escalates that appeal to an external reviewer (see 42 CFR §422.590(c) and (f) re: standard and expedited appeals, respectively). Also note that in the Medicare Advantage context, any adverse reconsideration of a plan's initial denial must automatically be escalated to an external reviewer, not just when a plan fails to meet applicable appeal deadlines (see 42 CFR §422.590). We believe that the same automatic escalation should occur in the context of group and individual health insurance coverage.

Continued Coverage Pending Outcome of Appeal

Interim final rule 45 CFR §147.136(b)(2)(iii) requires plans to provide continued coverage pending the outcome of an appeal. We believe that plans should be explicitly encouraged to waive any costs of coverage/treatment pending the outcome of an appeal should the outcome be unfavorable to the enrollee. In the alternative, at the very least, there must be explicit notice provided to the enrollee that if s/he loses their appeal, they may have to repay the costs of coverage/treatment.

Levels of Internal Review

We appreciate that interim final rule 45 CFR §147.136(b)(3)(ii)(G) requires a health insurance issuer offering individual health insurance coverage to provide for only one level of internal appeal before issuing a final determination. We believe that the underlying DOL regulation 29 CFR §2560.503-1(c)(2) and (3) should be amended to also require group health plans to only have one level of internal appeal before issuing a final determination. In our experience with Medicare private plan appeals, the second level of review by the plan that issued the initial adverse decision often upholds the denial and serves as an extra barrier and time delay for the enrollee in reaching any type of external review. If this recommendation is not accepted by the Departments, at the very least, participation in a second level of internal review should be voluntary on the part of the enrollee.

III. External Review

Scope of External Review

The final regulations should clarify that both state and federal external review processes must provide for external review of any final adverse benefit determination for which an internal appeals process is required. The language of interim final rule 45 CFR §147.136(c)(2)(i) can be read to limit external review to issues involving "requirements for medical necessity, appropriateness, health care setting, level of care, or effectiveness of a covered benefit." In conjunction with our comment above concerning the definition of an adverse benefit determination and the need for a full description of this term's scope, the final rule should articulate that both state and federal external review processes must review the broad range of adverse benefit determinations articulated in the preamble (p. 43332) as well as the underlying DOL regulation.

Individuals should also have the opportunity to appeal decisions concerning eligibility for a group health. For example, there may be a legitimate question over whether an employee works the requisite number of hours or has been employed the requisite number of days to be eligible for benefits under the group health plan. The regulations should require each group health plan sponsor to maintain an internal process for resolution of such disputes. The plan sponsor should be required to make information about the internal process available to current and potential plan participants.

NAIC Uniform Model Act – Minimum Standards

The preamble to the interim final rule notes that the Departments invite comments on the list of minimum consumer protections applicable to state external review processes and whether other elements of the NAIC Uniform Model Act should be included in the list (pp. 43335-6). We endorse inclusion of all of the Model Act provisions articulated in the preamble (with modifications, as discussed below) as well as the addition of the following consumer protections included in the NAIC model:

- ability to file internal and external appeals simultaneously for expedited review;
- external review is de novo;
- the carrier must immediately act to implement a reviewer's decision;
- the IRO must consider medical records, attending professional's recommendation, consultant reports, and practice guidelines in addition to carrier's criteria; and
- besides being accredited, among the qualifications for an IRO are that they must meet time frames for review, have qualified reviewers with relevant medical expertise and no conflicts of interest and no disciplinary history, maintain confidentiality, and have a phone system capable of receiving information at all hours and instructing callers.

Fees Charged to Beneficiaries

One of the elements of the NAIC Uniform Model Act that must be included in state external review process (if such process is to apply instead of the federal process) is that an issuer against which a request for external review is filed must pay the cost of an Independent Review Organization (IRO) for conducting the external review. 45 CFR §147.136(c)(2)(iv). This provision, however, also states that the "State external review process may require a nominal filing fee from the claimant requesting an external review" not to exceed $25 (or an annual limit of $75 in a plan year) and must be refunded if an adverse benefit determination is reversed through external review. In addition, the fee must be "waived if payment of the fee would impose an undue financial hardship". We object to any fee being imposed on a plan enrollee exercising his/her appeal rights, and such fees should be prohibited (or absorbed by the health plan or issuer). The imposition of fees is an additional barrier to accessing the appeals process, particularly when the appeals are urgent or expedited. If such fees are allowed, the enrollee should be able to demonstrate undue financial hardship simply through self-attestation instead of any form of demonstration. In no case should the failure to pay a filing fee prevent or delay an appeal from moving forward. Fees such as this are not allowed in the Medicare program and should also be prohibited for group and individual health insurance coverage.

Explanation of External Review Decisions

As referenced above, we appreciate the specificity and scope of information that plans and issuers must provide to a claimant when issuing an adverse benefit determination. See, e.g., interim final rule 45 CFR §147.136(b)(2)(ii)(C) and (E). We believe that any decision issued by either a state or federal external review process should be required to include the same level of specificity and scope of information relating to the bases upon which individual decisions are made, including any medical, legal or other standards either internal or external to the reviewing organization or entity.

Independent Review Organizations

We are concerned that the Independent Review Organizations referenced in the interim final rule (IROs) have the capacity to decide the full range of issues that arise on appeal. Some issues that consumers should be able to appeal necessitate a review of the health plan or issuer's adherence to its contract and to state and federal law. Independent Review Organizations that are comprised mainly of clinical reviewers are not the appropriate decision-makers for this type of case. Independent Review Organizations must also have legal expertise, including knowledge of the relevant state's laws and of federal law.

We are also concerned that for self-insured plans and others not subject to state review, there will still be inherent conflicts of interest if the plan contracts with IROs and pays them the expenses associated with a review. Such an arrangement becomes particularly problematic if compensation is tied to the number of appeals that are upheld.

We believe that utilization of a corps of state or federal administrative law judges, supported by appropriate clinical personnel, would address both issues of expertise and freedom from conflict of interest. As an alternative, it is preferable for federal or state regulators to contract with IRO entities with the appropriate legal and clinical expertise. The regulators should assign the IROs randomly to cases. The plan would then be responsible for reimbursing the government entity for the IRO expenses.

Judicial Review and Notice

We appreciate that the interim final rule requires plans or issuers at the internal claims and appeals level to provide a description of available internal appeals and external review processes, including information regarding how to initiate an appeal. See, e.g., 45 CFR §147.136(b)(2)(ii)(E)(3). The same information should be required to be provided by either plans or external review entities (e.g. Independent Review Organizations) following an adverse decision issued by an external reviewer. Information about any judicial review available to individuals following exhaustion of administrative review (both internal and external appeals), tailored to applicable information based upon the state in which an individual resides and the type of coverage s/he has, should be provided in a notice to that individual. Without such information, many claimants will be unaware of any rights they might have to seek additional review of their claim.

IV. Cultural and Linguistically Appropriate Notice

We appreciate efforts that the Departments are making to require that notices of available internal claims and appeals and external review processes be provided in a culturally and linguistically appropriate manner. We believe that the requirements outlined in the interim final rule, however, should be strengthened as follows.

Any rules relating to thresholds concerning the number or percentage of individuals who are literate in the same non-English language should be uniform and applicable to both group and individual coverage, regardless of the number of participants. Specifically, the requirement to provide notices in a non-English language should be triggered by the threshold that 10% or more of the population are non-English speaking per county. Also, if the individual is a speaker of a language that falls below the 10% threshold, a qualified interpreter should be made available to that individual for purposes of verbally interpreting the contents of the notice.

The preamble notes that "[p]lans and issuers are considered to provide relevant notices in a culturally and linguistically appropriate manner if notices are provided in a non-English language as described [in] [sic] these interim final regulations" (p. 43337). A footnote to this statement, however, places a limitation on the requirement that plans issue a determination involving urgent care within 24 hours by allowing plans to provide initial notice in English as long as follow-up notice is provided in an individual's non-English language (footnote 16 at p. 43337). We strongly object to this exception, and believe it should not be allowed. The process outlined in this footnote should not be deemed effective notice, so any appeal deadline clock should not start ticking for the beneficiary until valid notice is received.

In addition, outside of requirements relating to notice, plans should require that providers offer interpreters so that proper communication between providers and patients will occur during the actual provision of health care.

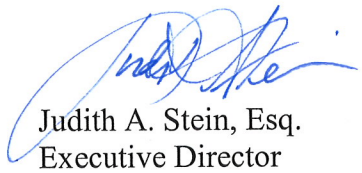
Finally, we concur with and incorporate herein the comments of the National Health Law Program (NHeLP) with respect to language access and this interim final rule.

V. Conclusion

Overall, we believe that the interim final rule provides for strong consumer protections. We thank you for the opportunity to submit comments.

Please feel free to contact Judith A. Stein (jstein@medicareadvocacy.org), Vicki Gottlich (vgottlich@medicareadvocacy.org), or David Lipschutz (dlipschu@medicareadvocacy.org) if you have any questions.

Sincerely,



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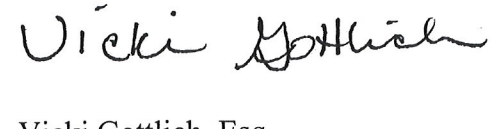

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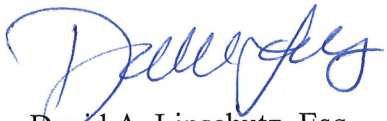

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