JUDGE DAVID L. BAZELON CENTER FOR MENTAL HEALTH LAW
Civil Rights and Human Dignity

September 21, 2010

Office of Consumer Information and Insurance Oversight
Department of Health and Human Services
Attention: OCIIO-9993-IFC, RIN 0991-AB70
P.O. Box 8016
Baltimore, Maryland 21244-1850

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
Attention: RIN1210-AB45

Internal Revenue Service
CC: PA: LPD: PR, Room 5025
P.O. Box 7604, Ben Franklin Station
Washington, DC 20044
Attention: REG-125592-10

Submitted electronically at www.regulations.gov

Re: Bazelon Center Comments on 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 (File Codes OCIIO-9993-IFC, RIN 0991-AB70/ RIN 1210–AB45/REG–125592-10)

To whom it may concern:

The Bazelon Center for Mental Health Law—a national legal-advocacy organization representing children and adults with serious mental illnesses—is pleased to submit the following comments 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. We appreciate the opportunity to provide feedback on these important regulations.

General Comments

We strongly support the Departments' efforts to provide robust regulations that ensure the protection of health insurance consumers, and continued

access to high quality, affordable care. We applaud the efforts of the Departments to honor the intention of the Affordable Care Act to ensure the protection of health insurance consumers, including those with serious mental illnesses.

Additional Comments

The Bazelon Center would like to submit additional comments on the following aspects of the interim final regulations:

I. Internal Claims and Appeals
II. External Reviews
III. Notices and Additional Provisions

Internal Claims and Appeals

The Bazelon Center applauds the issuance of the interim final rules by the Departments of Health and Human Services, Labor, and Treasury (collectively the Departments), as their promulgation marks an important step forward in creating a fair and uniform appeals process that guarantees internal review. We strongly support the following specific provisions regarding *internal* claims and appeals procedures:

(1) The internal claims and appeals processes of plans and issuers must provide for full and fair review of adverse benefit determinations including rescissions of health care policies;

(2) In the case of urgent care claims, plans and issuers must notify a claimant of a benefit determination (whether adverse or not) as soon as possible but not later than 24 hours;

(3) A plan or issuer must provide a claimant, free of charge, with any new or additional information or rationale regarding a claim as soon as possible and sufficiently in advance of a final adverse benefit determination;

(4) Plans and issuers must avoid conflicts of interest by ensuring that all claims and appeals are adjudicated in a manner designed to ensure the independence and impartiality of the persons involved in making the decision;

(5) Plans and issuers must provide notice to enrollees in a culturally and linguistically appropriate manner (this is also applicable to external review);

(6) The failure of plans and issuers to "strictly adhere" to all the requirements of internal claims and appeals processes with respect to a claim will allow a claimant to seek external review including judicial review if necessary; and

(7) Individuals in urgent care situations and individuals receiving an ongoing course of treatment may proceed with expedited external review at the same time the internal appeals process is pursued.

We encourage the Departments to consider clarifying and strengthening the regulations in a number of ways.

External Reviews

We also applaud the interim final rules that honor the intention of the Affordable Care Act to guarantee consumers an external review by an *independent* entity that is *binding* on a plan or issuer. The establishment of a right to external review is profound; until now consumers who receive coverage through plans governed by the Employee Retirement Income Security Act (ERISA) did not have the right to external review. Consumers had the option to appeal adverse benefit determinations, but Supreme Court case law instructed courts to provide deference to an ERISA plan's decisions.[1] Accordingly, the right to external review under the Affordable Care Act and its regulations is—in the words of one health policy scholar—"a complete game changer," especially given that the Department of Labor estimates that 77 million Americans receive coverage through ERISA plans.[2]

We encourage the Departments to consider the following recommendations to strengthen these robust regulations:

The Scope of External Review Should Include Review of Rescissions and Denials of Insurance Coverage Based on Eligibility

The scope of external review should be consistent with the scope of internal claims and appeals. Accordingly, we urge the Departments to expand the range of adverse benefit determinations that can be subject to state and federal external review processes. Under the interim final regulations, external review processes are required to assess a narrower set of adverse benefit determinations than internal appeals but little justification for this disparity is offered. We believe this disparity is not in the best interests of consumers and will lead to confusion and frustration with the appeals process. We, therefore, recommend that the scope of external review processes be equivalent to the scope of internal appeals.

A relatively broad range of adverse benefit determinations can be subject to internal claims and appeals. More specifically, the interim final regulations provide that for purposes of internal appeals, the term "adverse benefit determination" has the same meaning as the definition set forth at 29 CFR 2560.503-1 *plus* any rescissions of coverage. According to 29 CFR 2560.503-1(m)(4):

> The term "adverse benefit determination" means any of the following: a denial, reduction, or termination of, or a failure to provide or make payment (in whole or in part) for, a benefit, including any such denial, reduction, termination, or failure to provide or make payment that is based on a determination of a participant's or beneficiary's eligibility to participate in a plan, and including, with respect to group health plans, a denial, reduction or termination of, or a failure to provide or

1 *Firestone Tire and Rubber v. Bruch*, 489 U.S. 101 (1989).
2 Sara Rosenbaum, "Appeals of Claims for Benefits," Health Reform GPS, available at http://www.healthreformgps.org/resources/appeals-of-claims-for-benefits/ (accessed at September 16, 2010).

> make payment (in whole or in part) for, a benefit resulting from the application of any utilization review, as well as a failure to cover an item or service for which benefits are otherwise provided because it is determined to be experimental or investigational or not medically necessary or appropriate.

This definition of "adverse benefit determination" is considerably broader than standards used for purposes of external review processes. Under the interim final regulations, health plans and issuers are required to comply with either state or federal standards for external review. A state standard must provide, at a minimum, the consumer protections of the Uniform Health External Review Model Act developed by the National Association of Insurance Commissioners (NAIC Uniform Model Act). Accordingly, a state standard must provide for the external review of adverse benefit determinations only with regard to "medical necessity, appropriateness, health care setting, level of care, or effectiveness of a covered benefit."[3] This standard is unduly narrow as it excludes external review of rescissions and other adverse benefit determinations. Similarly, the federal standard is also narrow as it specifically excludes external review of adverse benefit determinations "based on a determination that a participant or beneficiary fails to meet the requirements for eligibility under the terms of a group health plan."[4]

We strongly recommend that the Departments require *all* adverse benefit determinations considered under internal review to be subject to external review under either state or federal law. Otherwise, consumers may not receive an impartial review of decisions made by health plans and issuers, decisions that could literally mean the difference between accessing critical health care treatment or not.

Standard of External Review

The interim final regulations do not explicitly state that independent review organizations (*i.e.* external review) must make a *de novo* (or fresh) assessment of adverse benefit determinations. Rather, the Department of Labor mentioned this standard of external review in sub-regulatory guidance and it is only applicable to the federal review process.5 A *de novo* standard of external review is important because it allows an objective review of the facts surrounding an adverse benefit determination. The importance of a *de novo* standard is evident by the fact that the NAIC Uniform Model Act provides for such a standard. **Given its importance, we strongly recommend that the Departments set forth a *de novo* standard of external review in their regulations, and that this standard be one of the minimum requirements for state review processes as well as an element of the federal review process.**

Evidence and Testimony

The statute and interim final regulations allow consumers to provide evidence and testimony during internal claims appeals. We believe that it is important for consumers to also have this

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3 45 CFR 147.136(c)(2)(i).
4 45 CFR 147.136(d)(1).
5 Department of Labor, Technical Release 2010-01, Interim Procedures for Federal External Review Relating to Internal Claims and Appeals and External Review under the Patient Protection and Affordable Care Act (August 23, 2010),

opportunity during external review, and request the Departments to include a regulatory provision that would permit consumers to provide evidence and testimony during external review. Further, we believe that both internal claims appeals and external reviews should (1) be non-adversarial in nature and not permit cross-examination of the enrollee by representatives of the health plan or health plan issuer, (2) should not require compliance with state or federal rules of evidence, and (3) should allow oral testimony. Such provisions would benefit consumers who may not be represented by counsel or other consumer advocates.

Requirement to Provide Continued Coverage Pending the Outcome of External Review

The statute and interim final regulations require plans and issuers to provide continued coverage pending the outcome of an *internal* claims appeals process. However, there appears to be no such requirement when consumers are pursuing external review of an adverse benefit determination. Continuation of coverage is important to ensure a fair external review, and it is especially important to individuals in urgent care situations and individuals receiving an ongoing course of treatment. People with disabilities and chronic conditions will be particularly susceptible to negative outcomes when services addressing a complex or serious medical condition are cut off during the course of an external appeal. **Accordingly, we strongly recommend the Departments to implement a regulatory provision that would require plans and issuers to provide continued coverage pending the outcome of external review**.

Applicability of Federal External Review Process in States without Universal Applicability of External Review Laws

The Departments have specifically requested comments on the issue of whether the federal external review process should apply to all plans and issuers in a state if the state external review process does not apply to all issuers in the state. This issue arises because some state external review processes do not apply to all issuers (e.g., state external review laws may be only applicable to HMOs and not other types of health coverage). In such instances, the federal government could apply its external review process only to health coverage not covered by state law or it could apply the federal process to all health coverage in a state.

We believe the more prudent option would be to have the federal process apply to all health coverage in a state. As noted by the Departments themselves, a central principle behind the interim final regulations is to create a uniform appeals process. Accordingly, the application of federal law to all health plans in states, having less than universal applicability of external review processes, would lessen confusion among consumers and increase efficiencies for plans and issuers.

Notices and Additional Provisions

The Bazelon Center commends the Departments for ensuring that consumers are provided with accurate and complete information about their rights responsibilities. We are particularly supportive of the provision that requires plans or issuers to include information about

government agencies and consumer assistance programs or ombudsman programs that can assist them with appeals when notifying consumers of their rights to appeal. We urge the Departments to consider the following recommendations regarding the consumer notifications and additional provisions in the interim final rules.

Notification Clarifications

We encourage the Departments to consider adding the following to the notification requirements:

- Plans should be required to include the correct address to which an appeal should be sent. If a consumer or consumer's representative has evidence that the appeal was sent to that address in a timely manner, such as a copy of the postmark, the appeal should be considered filed in time even if the insurer maintains that it has not received the appeal.

- The standard in §2715 of the ACA that mandates the provision of plan documentation and materials presented in a "culturally and linguistically appropriate manner and utilizes terminology understandable by the average plan enrollee," should be similarly applied to the notifications of appeals. For example, generalized terms, such as "experimental procedure not covered," or "not medically necessary" should be clearly defined and reference the specific criteria and standards on which the appeals decision was based.

- Plans should be required to state in the notice of adverse determination whether it believes that the plan is grandfathered pursuant to § 1251 and 10103 of the Affordable Care Act and § 2301 of the Reconciliation Act, and is, therefore, exempt from these interim final rules.

- Plans should be required to clarify that a letter from a consumer indicating intent to appeal does not constitute an appeal. Additionally, guidance should be issued to clarify that the a letter submitted by a consumer indicating intent to appeal should not be counted as the appeal, thus precluding the consumer from providing the documents and evidence necessary to submit a complete appeal.

- Plans should be required to inform consumers when the information submitted for an appeal is incomplete.

We also encourage the Departments to promulgate further guidance regarding the monitoring of health plans for violations of the prohibitions and consumer protections set forth in the Affordable Care Act, such as challenges to grandfathered status, or failing to provide mandated preventive services. There is a great need for a strong, well-defined mechanism for enforcement and oversight of plans, and suggest that additional guidance be included to describe such a mechanism. The regulations should also clarify who may submit challenges to a plan's adherence to these regulations (whether it be consumers, providers, state agencies, or advocacy organizations), as well as what entity will be responsible for reviewing such claims.

Disability-Appropriate Communication

The interim final rules require that health plans and health plan issuers provide notice to enrollees in a culturally and linguistically appropriate manner. However, the interim final rules make no mention of notices that ensure effective communication with enrollees with disabilities under either the Americans with Disabilities Act of 1990, as amended, or the Rehabilitation Act of 1973, as amended. The Bazelon Center, therefore, recommends that the final rule specifically require that health plans and health plan issuers ensure effective communication with respect to notices and appeals information when communicating with enrollees with disabilities, including the provision of notices in alternative formats.

Representation

Many consumers rely on their healthcare providers to support, and sometimes, initiate appeals on their behalf. Some healthcare providers and/or their clinical staff act on information about a whole or partial denial of their patients' benefits, and occasionally do so without their patient's full knowledge. Just as enrollees can mistakenly exhaust one or more appeal opportunities through lack of understanding about appeal procedures, clinicians can also inadvertently compromise their appeal rights by calling the health plan to discuss a denial or limitation in benefit.

The model notices and all other information about enrollees' appeal rights should explicitly state when or if the prescribing healthcare provider may act as an authorized representative for the purposes of exercising his/her patient's appeal rights. The NAIC model law discusses a consumer's right to designate a representative in writing. We believe that a right to representation is among the consumer protections in the model law and recommend that this right be included in federal regulations as one of the minimum protections.

Transition Period

Under the interim regulations, plans do not have to comply with the new rules until plan years beginning after July 2011, but they must be subject to binding reviews before then. We believe the final regulations should also immediately expand the scope of issues subject to review, using the new definition of adverse benefit determination for individual as well as group plans. Consumers need an immediate mechanism to appeal and assert the various rights that go into effect on September 23, 2010 under the Affordable Care Act. Plans and issuers should fully comply with the new process as of July 2011, not in health plan years that begin after that time. It will be easier to monitor the new appeals system and educate consumers about their rights if there is a clear date by which the system is effective. Though we understand that it may take until the next plan year for plans to conform their evidences of coverage and handbooks to explain the new requirements, they can begin providing appropriate information on claims denials on a given date that does not vary by plan year.

Medically Trained Decision-Makers of Claims Based on Medical Necessity

Although the interim final rule requires decision-makers to avoid conflicts of interest in order to

render impartial decisions, the rules do not require those making important claims decisions to have an appropriate degree of medical or clinical education and training when rendering a decision related to medical necessity or appropriateness. Because of this, the decisions of physicians and other providers who actually lay hands on patients are at risk of being overturned by individuals with no medical or clinical expertise. The interim final rule should require the final decision-maker at both the internal and external levels of appeal to have appropriate medical and clinical credentials to assess appeals based on medical necessity and appropriateness.

Similarly, we urge the Departments to ensure that reviews of legal issues are performed by reviewers with legal experience or expertise.

We thank you again for the opportunity to comment on these regulations, and appreciate your consideration of our proposed recommendation. We welcome the opportunity to discuss any of these thoughts in greater detail. Please contact Allison Wishon Siegwarth at 202-467-5730 x 113 or allisonw@bazelon.org for additional information or further clarification.

Sincerely,

Chris Koyanagi
Policy Director