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Office of Consumer Information and Insurance Oversight
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Ave., SW
Washington, DC 20201

Re: Interim Final Rules Relating to Internal Claims and Appeals and External Review Processes (RIN-0991-AB70)

Submitted via Federal eRulemaking Portal: www.regulations.gov

Dear Sir or Madam:

I am writing on behalf of America's Health Insurance Plans (AHIP) in response to the Interim Final Rules (IFR) regarding internal claims and appeals and external review processes. AHIP is the national association representing approximately 1,300 health insurance plans that provide coverage to more than 200 million Americans. Our members offer a broad range of health insurance products in the commercial marketplace and have demonstrated a strong commitment to participation in public programs.

AHIP members are committed to the successful implementation of the Affordable Care Act (ACA) and recognize the importance of an open and fair process for consumers to appeal benefit denials both through internal procedures established by health insurance plans and external review administered by independent third parties. While we strongly believe that consumers have benefited from these protections and support the vision laid out in the ACA for more uniform policies and procedures, we believe the IFR creates significant workability challenges.

We have undertaken an extensive process of working with our members to understand the scale and scope of these issues. Based on these discussions, we are providing specific examples of the operational concerns being raised and recommendations to address these issues. We very much appreciate the recent guidance from the Department of Labor establishing an enforcement safe harbor through July 1, 2011 which provides health insurance plans with flexibility in implementing several provisions of the IFR and ask that you use this time to work with stakeholders to address the workability issues that have been identified.

Workability of Specific Provisions of the IFR

Providing Useful and Timely Information about Denials and Appeals

The IFR requires the addition of diagnosis and procedure codes and descriptions to denial notices and to institute these changes, health insurance plans will include this information on Explanation of Benefits (EOBs) used to inform the primary subscriber of claim denials or approvals for any family member. The addition of such codes to EOBs (e.g., diagnosis or treatments for sexually transmitted diseases, cancer or genetic marker risks, or behavioral health conditions) raises significant privacy concerns under the federal HIPAA privacy rules and many state privacy laws given the highly sensitive and personal nature of the information that may be disclosed. There is a substantial risk that this information could be inadvertently disclosed to others, for example, if a subscriber opens mail or otherwise accesses an EOB for a spouse or child.

There are currently over 7,500 CPT codes and 17,000 ICD-9 codes in use. Adding these diagnosis and procedure codes in the notice presents administrative and operational challenges for processing benefit determinations requiring modifications to information technology systems, benefits administration, and notice formats and processing. EOBs currently include a description and date of the service and identification of the health care provider. Adding diagnosis and procedure codes and descriptions will increase the length and complexity of the EOB information beyond the one-page disclosure form provided in most cases today and may actually delay getting claims denial notices to claimants.

It is also important to recognize that consumers already have the ability to obtain diagnosis and procedure information directly from their health care providers. They may also access their health records at both the provider's office and the health insurance plan as required by the HIPAA privacy rule and many state privacy laws.

In addition, we note that that consumers, health insurance plans, and regulatory agencies have successfully used the current state and federal appeals process for many years without the necessity of CPT and ICD codes. We believe that any benefits that may result from including diagnosis and procedure codes on EOBs are outweighed by the privacy risks and administrative challenges and potential delays in providing this information. In some cases, disclosure of the codes may actually misinform consumers. For example, a clinician may submit a claim including secondary diagnoses considered as part of a physical exam, even though they do not reflect the individual's actual health status.

As an alternative to the IFR requirements, we suggest that diagnosis and procedure codes and descriptions could be included in the information provided to claimants as part of the appeals file

or the denial notice could include a statement advising claimants that the codes are available by request from the health insurance plan.

AHIP recommends the Final Rule allow inclusion of diagnosis and procedure codes in the appeals file provided to claimants or provide that the denial notice include a statement advising claimants they may obtain the codes by contacting the plan administrator or insurer.

Assisting Non-English Speakers

The IFR requires health plans to provide notices in a "culturally and linguistically appropriate manner" designed to assist claimants who are literate only in a non-English language. We support this important goal and believe the IFR should build on existing frameworks for providing language assistance established by the Medicare Advantage program and many states such as California and Massachusetts.

We believe there are alternative approaches being used successfully by health plans for assessing when members need such assistance. For example, plans might use the Medicare Advantage model for determining language needs in their service area or state where the coverage is offered. Another approach would follow the model used in states such as California where plans survey their membership to determine language needs. We emphasize that there is not a "one size fits all" approach to assessing language needs and there are a number of models in use today that should be considered.

This requirement also raises a number of technical and administrative challenges. First, health insurance plans must survey their employer clients to determine the percentage of group health plan participants with specific language needs. In the individual market, plans must assess the language needs based on the counties where their members reside. Once the lengthy process for determining the thresholds for providing assistance is completed, health insurance plans must include a statement in all notices, in those languages, that claimants can receive future notices in their language of choice. This raises particular challenges in states such as California because of the number of languages spoken and the need to add statements in all of those languages to each EOB. In addition, translating notices into another language, with reference to specific medical and contract terms, may delay the timely release of needed information to a claimant.

We also support giving plans flexibility in providing assistance to individuals once the language needs are determined. Translating a notice, with technical contract and medical terms, may not give claimants all the information they need (e.g., translating "grandfathered health plan" into another language does not communicate the context). Health insurance plans' long experience with their customers demonstrates that one-on-one communication between a member and a plan consumer representative in the speaker's language or providing translation or interpretation

services is often the best way to help those with limited English skills. As a result, we believe health insurance plans should be allowed to provide oral interpretation and other language services to members to assist with the appeals process, in lieu of translating notices into multiple languages.

AHIP recommends the Final Rule build on standards already in use by the Medicare program and by state language assistance laws and permit health insurance plans to assess the language needs of their members by either: (a) assessing the number of non-English proficient residents in the plan's service area or state; or (b) surveying their members to determine the number of non-English speakers. We also recommend that health insurance plans be given flexibility in the provision of language assistance by allowing the use of oral interpretation or translation services or by making consumer assistance services available in the consumer's primary language. In addition, AHIP recommends that the health insurance plans that are compliant with state or federal laws that meet or exceed the IFR standards be deemed compliant.

Responding to Urgent Care Claims

Currently, the ERISA claims procedure rule and most state laws permit health insurance plans to respond to requests for services involving urgent care within 72 hours, although notices must be provided in a shorter time period if required by the medical condition of the claimant. The IFR shortens this period for responding to urgent care claims to 24 hours.

It is important to understand that an urgent care claim is not a medical emergency, in which case a patient is given immediate care and coverage is provided by the health insurance plan without the need for prior authorization. Rather, an urgent care claim involves a prior authorization for a benefit in which the claimant's medical condition makes the usual time frame for responding (15 days in the case of the ERISA claims procedure rule) too long. For example, an individual might be stabilized in an emergency room after an automobile accident. The treating physician may want to request additional medical services which require prior authorization and 15 days is too long to respond. In such case, under the ERISA rules and many state laws, the health insurance plan must respond to the request, as soon as possible given the individual's medical condition, but no later than 72 hours.

Shortening the outside limits of this time frame from 72 hours can raise administrative challenges, especially when it is difficult to obtain information from the medical facility where the individual is being treated or a referring health care provider is not available for consultation because of a weekend or holiday. Giving health insurance plans flexibility to use this full period, if necessary, to investigate a non-emergency claim and request additional information does not disadvantage the individual because any medical emergencies are treated and coverage is

provided. The purpose of the urgent care response time limit is to recognize situations where the full response time limit for a prior authorization review may be too long.

AHIP recommends that the Final Rule retain the current limits in the ERISA claims rule and many state laws requiring a response to an urgent care claim within 72 hours, unless a shorter time is necessary given the individual's medical condition. In addition, the agencies should modify the definition of "urgent care claim" to more clearly distinguish between emergency care situations and cases where the full response time limit for prior authorizations is too long based on the claimant's medical condition.

Making Newly Obtained Evidence Available

The IFR requires health insurance plans to make available to claimants all new evidence generated in connection with the investigation of an appeal in advance of the final decision. While we fully support giving claimants all information developed during an appeal, there may be situations where there is not enough time to provide such information within established state or federal deadlines for reaching a decision (e.g., California has a 30 day limit for all claims).

Many states establish a fixed outside deadline for health insurance plans to reach a decision on a claim for benefits. The ERISA claims procedure rule also sets limitations on how long a plan may take to provide notice to a claimant regarding an appeal. Failure to meet these deadlines subjects the health insurance plans to regulatory penalties and/or potential litigation risk (as explained below, these risks are increased by the IFR changes allowing claimants to proceed directly to external review or to court for any failure by a plan to strictly adhere to the rules, even if *de minimis*).

Health insurance plans may need the full timeframe to fully investigate the claim, especially in situations where medical or other information is requested from a treating health care provider or a medical review is performed by an outside consultant. As a result, a health insurance plan may not have gathered all of the information generated in connection with the claim until the last one or two days of the time period to reach a decision and provide notice.

As a practical matter, health insurance plans will generally consider a new response or evidence from a claimant once a final decision has been reached, and prior to the external review process. If supported by the evidence, the plan will agree to pay a previously denied claim for benefits as an alternative to external review or litigation.

AHIP recommends that health insurance plans be permitted to provide claimants with all evidence generated during the appeal process within the time frame for reaching and providing notice of a decision.

Internal Appeals by Health Insurers in the Individual Market

The IFR follows current state and federal requirements for claim appeals by permitting two levels of review for claimants covered by a group health plan. In many cases, insurers in the individual market also provide two levels of review for an appeal of a benefit denial. The IFR, however, will now limit consumers with coverage in the individual market to only one level of internal appeals.

We believe consumers in the individual market should continue to have a right to two levels of internal review. It is entirely possible that a second review will uncover additional medical or other information from the claimant or from his or her health care clinician that had not been provided earlier that would lead to a decision to approve the claim.

We note that the IFR contains standards to assure the fairness and independence of the review process and that a second level of appeal must be handled by a different reviewer. We believe these safeguards protect the review process and that consumers who have coverage in the individual market should continue to have access to two levels of appeals with the insurer.

AHIP recommends that insurers in the individual market be permitted to provide two levels of review for an appeal of an adverse benefit determination in the same manner as allowed for group health plans and as permitted in many states.

Allowing Plans and Claimants to Resolve Internal Appeals

The IFR creates a new standard for health insurance plans by providing that a claimant may proceed directly to external review or to litigation for any failure by the plan to strictly comply with the provisions of the IFR. The internal appeals process is designed to give individuals full and fair review of benefit determinations and we believe both consumers and health insurance plans should be given reasonable opportunity to follow the internal appeals process prior to external review or litigation. A *de minimis* failure by a health insurance plan to comply with the IFR should not automatically result in a disruption of the internal appeals process (e.g., if a plan misses a notice deadline by one day it should force the plan and claimant to external review).

We believe that requiring claimants to first exhaust their remedies with the plan or insurer does not limit their ability to have a decision submitted to external review or to judicial consideration and, in fact, provides the most effective and efficient way to handle benefit determinations.

AHIP recommends that plans be permitted to correct minor procedural errors and continue with the internal appeals process instead of proceeding directly to external review or litigation.

Allowing Sufficient Time to Establish External Review Procedures

The IFR sets out new requirements for external review of adverse benefit determinations for self-funded group health plans and for insurers in states without existing state review requirements (46 states and the District of Columbia currently have such review laws). While additional flexibility was provided in setting up new external review processes, there are a number of implementation challenges including establishing contracts with three Independent Review Organizations (IROs) (in the case of self-funded group health plans) and processes to submit reviews to the Office of Personnel Management (OPM) (for insurers in states without external review systems).

We question the availability of existing IROs to meet the demand – for example, hundreds of thousands of self-funded group health plans must each contract with three accredited IROs or must arrange for a review process through their Third Party Administrator. In addition, as discussed below, the scope of external reviews for these health insurance plans has been significantly expanded to include non-medical issues such as whether a requested service is a covered benefit. The expansion of the types of issues that will be submitted to external review places additional administrative burdens on the existing IRO structure and on the capacity of OPM.

AHIP recommends that self-funded group health plans and health insurance issuers in states without an established external review process be given sufficient time to establish an external review framework, including the requirement to set up contracts with IROs. An additional enforcement safe harbor should be established allowing health insurance plans that currently do not have an external review option until plan or policy years on or after July 1, 2011 to initiate external review procedures. In addition, as discussed below, consideration should be given to limiting the scope of external review to situations involving denials based on medical necessity, experimental or investigational treatments or appropriateness of care or settings of care as provided under state external review laws and the NAIC Model Act.

Clarifying the Scope of the External Review Process

The IFR creates a new set of external review procedures for self-funded group health plans and for health insurance issuers in states that do not currently have a review process. This new process is different from that found in the NAIC Model Act, which is the standard established by the ACA, and from what is followed in almost all of the states with external reviews which address denials based on medical necessity, experimental or investigational treatments, or appropriateness of care or settings of care.

The new federal process covers not only medical review denials but also includes decisions that a service is not covered by an insurance policy or benefit plan. For example, a health insurance plan may cover 20 out-patient therapy visits on an annual basis, unless additional therapy is authorized by a treating health care provider. The individual may refuse a medical evaluation, but insist on additional therapy. The new process would submit the dispute to external review by an Independent Review Organization (IRO), even though no medical decision making is at issue.

We believe external reviews should follow the successful process established by state external review laws and by the NAIC Model Act for submitting denials based on medical necessity, experimental or investigational treatments, or appropriateness of care or settings of care.

AHIP recommends that the external review process for self-funded group health plans and for insurers in states without an external review process apply to reviews of adverse benefit determinations by a plan or insurer based on medical necessity, investigational or experimental treatment, or appropriateness of care or settings of care.

Clarifying the Application of the standards to Major Medical Coverage

The IFR is intended to provide a process for claimants to appeal the adverse benefit determinations by group health plans and health insurance issuers in the individual and group markets with respect to major medical coverage. We request acknowledgement that the IFR applies to comprehensive, major medical coverage, and not to the benefits classified as "excepted benefits" under subsection 2791(c) of the Public Health Service Act. The inapplicability of the Affordable Care Act's insurance and market reform provisions to excepted benefits has been previously acknowledged for the new Internet portal and in the preamble of the Interim Final Rules for Grandfathered Health Plans, and we ask that the same recognition also be made with respect to this IFR.

AHIP recommends that the agencies clarify that the IFR is intended to apply to major medical coverage provided by a group health plan or by a health insurance issuer and not to coverage defined under the Public Health Service Act as excepted benefits.

Suggestions for Addressing These Issues

As we offer our suggestions for moving forward, we want to reiterate that our members strongly support the right of consumers to participate in internal appeals and external review processes. All states currently have requirements for internal appeals and 46 states and the District of Columbia have external review laws. The NCQA reviews and provides accreditation for health insurance plan appeals processes and URAC provides accreditation for organizations that administer external review programs at the state level. In addition, the NAIC has developed a

model, which we support, to create greater uniformity in external review. The ACA requires this model to serve as the framework for all state and federal external review processes.

Our members have been working hard to understand the elements of the IFR and how the proposed procedures would work. While we appreciate the enforcement safe harbor recognized in the guidance released yesterday, given the significant operational challenges they have identified, we believe the Department should consider allowing additional time to assess the impact of the proposals, make revisions to address the workability issues, and create a transition period before the new regulations take effect. Specifically, we recommend that the effective date for all provisions of the IFR be delayed to plan and policy years starting July 1, 2011.

During the transition period, you could deem health insurance plans that are complying with state appeals and review requirements and the ERISA rules as meeting the ACA provisions while they work to implement the IFR. It is important to recognize that consumers already have protections through extensive state and federal requirements for internal appeals and external review. These provisions provide safeguards that are compliant with the ACA's internal claims appeals and external review provisions. A delay in the compliance date to allow changes to the rules will not penalize individuals who are challenging claim denials. Rather, it will give everyone more time to "get it right" in terms of establishing an appeals process that works for consumers, but does not add additional cost or complexity.

AHIP's members have been leaders in supporting internal appeals processes and external review and are strongly committed to an open and timely process for resolving benefit decisions. We look forward to working with you and your colleagues at the Departments of Labor and the Treasury in addressing these important issues.

Sincerely,

Jeffrey Gabardi
Senior Vice President