

**America's Health
Insurance Plans**

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July 25, 2011

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201

Re: Amendment to Interim Final Rule on Internal Claims and Appeal and
External Review Processes

Submitted Electronically: www.regulations.gov

Dear Sir/Madam:

America's Health Insurance Plans (AHIP) is writing in response to the Amendment to the Interim Final Rule (IFR) on the Internal Claims and Appeals and External Review Processes. The Amendment was published by the Departments of Health and Human Services, Labor, and the Treasury (the "Departments") in the *Federal Register* on June 24, 2011 (76 Fed. Reg. 37208).

AHIP is the national trade association representing the health insurance industry. AHIP's members provide health and supplemental benefits to more than 200 million Americans through employer-sponsored coverage, the individual insurance market, and public programs such as Medicare and Medicaid. AHIP advocates for public policies that expand access to affordable health care coverage to all Americans through a competitive marketplace that fosters choice, quality, and innovation.

As discussed in our comments, we believe the Amendment makes a number of important modifications to the IFR which will streamline the procedures for the internal appeals and external review of adverse benefit decisions while preserving important consumer protections. Our comments are intended to support the changes in the Amendment and to recommend additional revisions to strengthen the provisions of the IFR.

Informing Claimants About Benefit Decisions

AHIP supports the requirement in the Amendment for group health plans and health insurance issuers to provide additional information about the benefit decision on request. The Amendment

July 25, 2011

Page 2

requires group health plans and health insurers to provide diagnosis and treatment codes and their meanings to claimants on request and in a timely manner. A request for a diagnosis and treatment code may not be treated as a request for an internal appeal or external review.

We believe that providing the codes on request will inform consumers about the benefit decision while allowing group health plans and insurers to protect the privacy of the individual's health information as required by federal and state confidentiality laws. This approach also addresses situations where diagnosis and treatment codes were not submitted in connection with the claim for benefits (e.g., utilization review determinations or pre-service claims).

Providing Information in a Culturally and Linguistically Appropriate Manner

The Amendment establishes a process for group health plans and health insurers to assist enrollees that have difficulty speaking or understanding English through the provision of language assistance services and the translation of notices into other languages on request. These requirements are triggered if at least ten percent of the population where the claimant resides speak a particular non-English language and speak English less than "very well" as determined by the United States Census Bureau.

AHIP supports the procedures in the Amendment to help individuals who do not speak English as their primary language with the appeal of an adverse benefit determination. Our members currently provide a wide array of assistance to meet the cultural and language needs of their customers.

The Amendment allows group health plans and insurers to pair the claimant and a customer services representative with a translator who can facilitate a discussion about the benefit determination and the individual's appeal rights. This is a consumer focused process that will help resolve cultural or language barriers. If necessary, the written adverse benefit determination can be translated into the individual's primary language.

The Preamble to the Amendment asks if health insurers should be required to provide additional language assistance services if requested by a group health plan sponsor. In fact, health insurers and third-party administrators are providing such assistance today as required by contract with the plan sponsor, and based on the needs of the employer and its employees. We do not believe additional regulation is necessary at this time.

Urgent Care Claims

The Amendment requires group health plans and health insurers to respond to a request to approve an urgent care, pre-service claim as soon as possible, taking into account the medical exigencies of the individual, but not later than 72 hours after receipt of the request for coverage.

July 25, 2011

Page 3

The health insurer or group health plan must defer to the attending health care provider's determination whether the claimant's condition involves urgent care.

We believe the standard sets the appropriate outside time limit for handling urgent care situations. The Affordable Care Act (ACA) and enabling regulations require group health plans and health insurers to automatically provide coverage for emergency care without imposing cost-sharing where the life or health of the patient is in immediate danger.¹ An "urgent care" situation typically involves requests for health care services that are not medical emergencies, but that require timely decision making (e.g., a request to approve certain follow-up treatments after a patient has been stabilized at the hospital). Allowing the group health plan or health insurer to take up to 72 hours to approve such services will not place the individual in immediate harm.

There is however one issue with respect to this standard that should be addressed by the Departments. The Amendment requires the group health plan or health insurer to defer to the determination of the "attending health care provider" regarding the claimant's medical condition. The original ERISA claims rule provided that any determination by "a physician with knowledge of the claimant's medical condition" that the claim involved urgent care was binding on the group health plan or group health insurer (29 C.F.R. 2560.503-1(m)(1)(iii)). This requirement was not changed by the IFR or the Amendment. We believe that a physician who is knowledgeable about the patient's condition is in the best position to affirm that the requested services are an "urgent care claim." As a result, the health plan or health insurer should be permitted to require that the judgment regarding the patient's urgent care situation be made by a physician with an understanding about the individual's medical status.

Recommendation

AHIP recommends that the standards applicable to a request to approve urgent care services continue to require that the group health plan or health insurer defer to the determination of an "attending health care provider with knowledge of the claimant's medical condition" regarding whether the situation involves urgent care rather than requiring deference to an "attending health care provider." Health plans and health insurers should not be required to automatically defer to the judgment of a health care provider who has not examined the patient or reviewed his or her medical records to determine if an urgent care situation exists.

Clarifying the Effective Date of the IFR and Amendment

In addition to the IFR and Amendment, the Departments have released numerous technical guidance documents, frequently asked questions guidance, and model notices. While these materials have helped to further clarify the requirements with respect to claims internal appeals

¹ See: 45 C.F.R. §147.138(b)

July 25, 2011

Page 4

and external review, the effective dates of the various provisions are not entirely clear. For example, the Preamble to the Amendment states that “(a)t the expiration of the enforcement grace period, the Departments will begin enforcing the relevant requirements of the July 2010 regulations as amended by this rulemaking.” (76 Fed. Reg. 37210). We understand this to mean that the changes made by the Amendment (the “relevant requirements”) were effective July 22, 2011 (the effective date of the Amendment published in the *Federal Register*), but that there is an enforcement safe harbor for those provisions that will remain until plan or policy years on or after January 1, 2012. Accordingly, “(d)uring the grace period, the Department of Labor and the IRS will not take any enforcement action against a group health plan, and HHS will not take any enforcement against a self-funded nonfederal governmental health plan, with respect to these provisions.” (Technical Release 2011-01, March 18, 2011 at p. 4).²

The determination of the implementation deadlines for the various provisions of the IFR is further complicated by the interaction with state laws addressing internal appeals and external review. As discussed below, we are waiting for HHS to issue a determination regarding the states that are in compliance with the ACA requirements for external review and where states may need to enact additional statutes or regulations. It is also not clear where a state law may be preempted by the IFR.

We believe it is critical for the agencies to provide further clarification regarding the implementation dates of the various provisions of the IFR, the Amendment, and the technical guidance. Group health plans and health insurers are working diligently to implement the provisions but would benefit from additional understanding of their compliance deadlines.

Recommendation

AHIP recommends that additional guidance be issued clarifying when the various provisions of the IFR as modified by the Amendment and the guidance materials must be implemented. This guidance should clearly explain the interaction of the IFR provisions with state requirements.

Allowing Two Levels of Internal Appeals in the Individual Insurance Market

Although not addressed in the Amendment, our members continue to raise concerns regarding a provision in the IFR which prohibits a health insurer from providing two levels of internal appeal for claimants with coverage in the individual insurance market. We believe insurers in the individual market should be permitted, but not required, to provide a second level of internal appeal. In many cases, additional information about the claim is provided by the claimant or the

² Technical Release 2011-01 is silent with respect to whether HHS will follow a similar enforcement safe harbor for health insurers although it does encourage “States to provide similar grace periods with respect to issuers, and HHS will not cite a State for failing to substantially enforce PHS Act section 2719(a) in these situations.” (Technical Release 2011-01 at p. 4).

July 25, 2011

Page 5

health care provider allowing the health insurer to approve the benefit. A second level of appeal provides claimants with more efficient and effective means to address an adverse benefit determination, rather than going to external review.

We note the ERISA claims procedure rule and the IFR include extensive standards to avoid conflicts of interest on the part of reviewers and to assure the second level of review is made independently.³ It is not clear why claimants in the individual market need to immediately go to external review after the first level of appeals has been completed rather than permitting them to ask the insurer provide a second review of an adverse benefit determination.

Recommendation

AHIP recommends that the IFR allow, but not require health insurers to provide a second level of internal appeals for claimants in the individual insurance market.

“Deemed Exhaustion” of the Internal Appeals Process

The Amendment addresses situations where a claimant is allowed to bypass the internal appeals process and proceed directly to external review or litigation. The Amendment provides the claimant may request external review or court review and does not have to first exhaust their internal appeal remedies if the group health plan or health insurer violates any of the requirements of the rule. There is an exception, however, to this “strict adherence” standard if the rule violation: (1) was *de minimis*; (2) did not cause prejudice or harm to the claimant’s right to external review; (3) was attributable to good cause or matters beyond the plan’s or issuer’s control; (4) is not reflective of a pattern or practice of non-compliance by the health insurance plan; and (5) was in the context of an ongoing good-faith exchange of information. If the IRO or court determines violation of the rule by the plan or insurer meets this complicated, five-part test the claimant will be required to re-submit the adverse benefit determination for internal appeal.

We appreciate the Amendment’s efforts to balance the rights of claimants to due process against the cost and administrative burdens of external review or litigation where the violation of the rule by a group health plan or insurer is minimal and does not prejudice the claimant. As we have noted in prior comments, in the vast majority of situations, the internal appeal of an adverse benefit determination will satisfactorily resolve the dispute and it makes little sense to skip this process and to proceed to external review or litigation if it is not necessary. We continue to be concerned that the “deemed exhaustion” standard sets a too high bar for group health plans and health insurers for minor rule violations where the claimant’s rights to due process are not at risk.

³ See: 45 C.F.R. §147.136(b)(3)(ii)(D).

July 25, 2011

Page 6

The Amendment provides that the determination of whether the plan or insurer has failed to follow the rule (thereby giving the claimant the right to proceed to external review or litigation) will be made by the external reviewer (in this case, an Independent Review Organization or “IRO) or the court. We suggest that the test to determine whether the plan or insurer has complied with the rule be simplified. The determination should be based on two basic issues: (a) was the violation of a *de minimis* nature and (b) did it cause prejudice or harm to the claimant’s right to external review. If the rule violation was significant and prejudicial or harmful to the claimant, it is entirely appropriate to ask the IRO or court to make a decision on the adverse benefit determination. We believe these two issues provide a better guide for claimants – and for IROs and the courts – to determine when it is not possible to provide a full and fair internal appeals process.

In making this determination, the IRO or court may want to examine whether the violation was due to good cause or involved the good faith exchange of information, but these factors should not be determinative. For example, the receipt of a notice by a claimant may be delayed for a short period of time thereby missing the deadlines in the rules for providing notice. Whether the delay was due to the fault of the health plan/insurer, the claimant or a third-party such as the U.S. postal service is irrelevant to a determination of whether the delay was *de minimis* or prejudicial to the claimant.

There is a legitimate concern about on-going practices or patterns of non-compliance by a group health plan or health insurer in the administration of internal appeals and external review. We believe these concerns are better addressed through enforcement action by state and federal regulators, rather than by an IRO or court that will likely not have knowledge of or experience with the day-to-day processing of appeals by a plan or insurer to determine if the violation is part of an overall pattern or practice.⁴

Recommendation

AHIP recommends that the standard for an IRO or court to determine if a group health plan or insurer has complied with the requirements regarding the internal appeal of adverse benefit determinations should be: (a) was the violation by the plan or issuer *de minimis* and (b) did the violation cause harm or prejudice to the claimant’s right to external review. If the IRO or court determines that failure by the group health plan or health insurer to comply with the rule was not *de minimis* and was harmful or prejudicial to the claimant’s right to external review, the individual should be permitted to skip the internal appeals process and proceed directly to external review or to litigation, as appropriate.

⁴ We would also note that under ERISA and many state insurance codes, individuals have the right to ask the courts to address unfair patterns or practices by plans or insurers. *See*: 29 U.S.C. §1132(a)((3).

External Review – Scope of Review for Self-Funded Group Health Plans

The Amendment modifies the scope of external review for self-funded group health plans. The Amendment provides that the “federal” external review process for self-funded plans shall apply to a rescission of coverage and to “an adverse benefit determination . . . that involves medical judgment (including, but not limited to, those based on the plan’s or issuer’s requirements for medical necessity, appropriateness, health care setting, level of care, or effectiveness of a covered benefit); or its determination that a treatment is experimental or investigational)” (29 C.F.R. §2590.715-2719(d)(1)(ii)(A)). The IFR originally required that all adverse benefit determinations by self-funded group health plans, including those based on issues related to the terms of the coverage (i.e., contract disputes as opposed to decisions based on medical judgment), should be submitted to external review. The Amendment notes that limiting external review to medical judgment issues is a “temporary” suspension of the broader scope of external review for self-funded plans which may, according to the Preamble to the Amendment, be lifted by January 1, 2014.⁵

The scope of external review for self-funded plans established by the IFR exceeds the scope of review as defined by ACA Section 10101(g) which requires plans or issuers to comply with an external review process that, “at a minimum includes the consumer protections set forth in the Uniform External Review Model Act” as promulgated by the National Association of Insurance Commissioners. The NAIC Model Act provides that an “adverse benefit determination” subject to external review is a denial based on a determination “does not meet the health carrier’s requirements for medical necessity, appropriateness, health care setting, level of care or effectiveness”⁶ This is the same review standard used by almost all states with external review procedures.

It is not clear why the Federal review process for self-funded group health plans should be different from that followed by the states in the case of health insurers. Most IROs conduct reviews based on health insurer decisions involving medical necessity, appropriateness of care or settings of care, or experimental or investigational treatments. We believe the scope of external review for self-funded group health plans should be directed where there is the most need – issues involving a medical judgment by the group health plan where a “second opinion” by an IRO would be helpful to a final determination. Expanding the scope of review to include all benefit determinations will significantly increase the complexity of external review and add to the cost of health coverage.

⁵ 76 Fed. Reg. 37216.

⁶ NAIC Model Act Section 3 (A).

July 25, 2011

Page 8

Recommendation

AHIP recommends that external review for self-funded group health plans focus on rescissions and on decisions based on medical judgment and that the “temporary suspension” of the scope of review for such plans be made permanent.

External Review – Scope of Review for Insurers in the Individual Market

There continues to be questions regarding the appropriate scope of external review for issues related to the eligibility to purchase coverage in the individual market. As you are aware, these decisions may be based on medical issues (e.g., medical rider placements) or on other considerations (e.g., coverage denial because the applicant lives outside the insurer’s service area). The Preamble to the IFR makes clear that “these interim final regulations expand the scope of the group health coverage internal claims and appeals process to cover initial eligibility determinations for individual health insurance coverage.” (75 Fed. Reg. 43334). Less clear is whether the state external review process envisioned by the IFR and guidance involves eligibility determinations that are based on medical issues. This question has been raised because the state process is directed to adverse benefit determinations “based on the issuer’s (or plan’s) requirements for medical necessity, appropriateness, health care setting, level of care, or effectiveness of a covered benefit.” (45 C.F.R. §147.136(c)(2)(i)). Arguably, a coverage denial based on a medical issue, such as a medical rider, is not a decision based on medical necessity, appropriateness, health care setting, level of care, or effectiveness of a covered benefit and, as a result, not subject to external review.

This question is further complicated by the application of the “federal” external review standards for states that are determined by HHS not to be in compliance with the NAIC standards as discussed below. In such case, the health insurer will be expected to either follow the standards set out in guidance or to contract with HHS to conduct the external review. The scope of review under the federal standard is the same as the state standards in the IFR, whether the decision “was based on medical necessity, appropriateness, health care setting, level of care, or effectiveness of a covered benefit.” (Technical Release 2011-02 at p. 2). We believe the Departments should clarify whether external review for the individual insurance market, whether under the IFR or the Technical Release includes eligibility determinations.

External Review – Exercise of Medical Judgment

The Amendment includes examples of adverse benefit determinations that are based on medical judgment (45 C.F.R. §147.136(d)(1)(iii)). The Preamble to the Amendment also provides “(a)dditional examples of situations in which a claim is considered to involve medical judgment” (76 Fed. Reg. 37216) The examples are important because the IFR and the Amendment provide that external review under both the state and federal process is reserved (in addition to

July 25, 2011

Page 9

rescissions) to cases where the adverse benefit determination is based on medical judgment. We believe that several of the examples do not involve a determination based on medical judgment and should be revised accordingly.

(1) Whether a participant or beneficiary is entitled to a reasonable alternative standard for a reward under the plan's wellness program (Amendment Preamble).

As noted, in the Preamble, group health plans and health insurance issuers that require individuals participating in a wellness program to meet a health standard (e.g., achieving a specific weight loss target) in order to obtain a reward, must also provide a reasonable alternative standard if the participants are unable to meet the original benchmark due to a medical condition.

We do not believe that a determination regarding participation in a wellness program is an "adverse benefit determination" subject to the claims rule. Subjecting such programs to extensive notice and appeal processes may force employers to stop offering such options to their employees. In addition, even if a wellness program were considered a "claim for benefits," in most cases, the decision whether an individual is unable to meet the original benchmark is made by their own physician.⁷ It makes little sense to subject such determinations, made by the individual's own health care provider, to an appeal and to consider the determination as a "medical judgment" of the health plan or insurer.

(2) Whether a plan is complying with the nonquantitative treatment limitation provisions under the Mental Health Parity and Addiction Equity Act and its implementing regulations (Amendment Preamble).

A health plan's or insurer's compliance with the so-called "nonquantitative" treatment limitations in the mental health parity rules is entirely different from an adverse benefit determination by the plan or insurer based on a medical judgment.⁸ Most of the examples provided in the mental health parity rules of nonquantitative treatment limitations have nothing to do with medical issues (e.g., standards for provider admission in a network, plan methods for determining usual, customary, and reasonable charges).⁹

⁷ See: Department of Labor, Field Assistance Bulletin No., 2008-02, February 14, 2008 at p. 5 ("It is permissible for the plan or issuer to seek verification, such as a statement from the individual's physician, that a health factor makes it unreasonably difficult or medically inadvisable for the individual to satisfy or attempt to satisfy the otherwise applicable standard").

⁸ As we noted previously in our comments on the mental health parity interim final rules, the Mental Health Parity and Addiction Equity Act does not address issues related to nonquantitative treatment limits and the rules incorrectly set forth such requirements.

⁹ See: 45 C.F.R. 146.136.

July 25, 2011

Page 10

Where the examples of nonquantitative treatment limitations arguably touch on medical issues, the determination of “parity” in the coverage of medical/surgical benefits and behavioral health/substance use disorder benefits with respect to such limits has nothing to do with a denial of coverage based on medical judgment. For example, whether a plan correctly applies behavioral health utilization review standards to a request to cover such services is an appealable medical judgment, however, variations in utilization review standards between medical/surgical benefits and behavioral health/substance use disorder benefits is not. The appropriate remedy for a violation of the parity standards is an enforcement action by the appropriate federal regulatory agency, not an appeal by a plan participant of an “adverse benefit determination.”

(3) Whether a service should be provided out-of-network because it cannot be “effectively provided” by an in-network health care provider (Amendment).

A decision whether to allow an enrollees to go out-of-network for a service or treatment that is otherwise available in-network is generally not a medical decision. Whether services may be effectively provided in-network are based on a number of factors including the qualifications of the health care provider, the location of the treatment facility, and the availability of treatment or services on a timely basis. If a health insurer requires patients to obtain an MRI from an in-network provider that determination is not made on a medical judgment applied to the individual’s health condition. If the insurer is somehow at fault (for example, if there are not enough MRI facilities in-network to provide access on a timely basis) the remedy is an enforcement action by the state insurance regulators based on a violation of network adequacy standards. The failure to provide access to out-of-network providers is not a medical judgment that should be subject to internal appeal and external review.

Recommendation

AHIP recommends that the examples involving wellness program participation, application of “non-quantative” treatment limits for purposes of meeting the mental health parity rules, and application of in-network provider requirements be deleted as they do not involve an adverse benefit determination or the exercise of medical judgment.

Continue to Allow Self-Funded Group Plans to Voluntarily Meet State Standards

Technical Release 2010-01 from the Department of Labor established federal standards for the external review of adverse benefit determinations by self-funded group health plans. As an alternative to those standards, the Technical Release recognizes that a self-funded plan may choose to comply with applicable state external review procedures if the state permitted such plans to participate in the external review process.

July 25, 2011

Page 11

Technical Release 2011-02, issued by the Department of Labor contemporaneously with the Amendment, clarifies several issues regarding the federal external review process as it relates to contracts between a self-funded group health plan and an IRO. It is not clear, however, whether this new guidance will continue to allow self-funded group health plans the option to follow state external review procedures.

Recommendation

AHIP recommends that the Department of Labor clarify that a self-funded group health plan is permitted to voluntarily comply with state external review procedures as an alternative to compliance with the federal standards set forth in Technical Release 2010-01 as modified by Technical Release 2011-02.

Allow Sufficient Time for States and Insurers to Meet New External Review Standards

The Preamble to the Amendment and agency guidance issued at the same time as the Amendment clarify that the Department of Health and Human Services (HHS) will issue a determination on or before July 31, 2011 whether a state's laws are in conformity with the consumer protection provisions of the NAIC Uniform Health Carrier External Review Model Act. If the state is not in conformity, health insurance issuers (and non-federal governmental plans) in the state have the option to either comply with external review standards set forth in Technical Release 2011-02 or they may allow the review to be conducted by HHS through an agreement with the Office of Personnel Management (OPM). A state may request that HHS make a redetermination of its decision whether its laws are in conformity with the NAIC Model Act, and the federal agency must make its decision on the request by October 1, 2011.

There are a number of critical issues with respect to this process. First, it is important for HHS to clearly enumerate where a state's laws may not meet the consumer protection standards of the NAIC Model and what changes to the law are required. In addition, where the differences are not significant, HHS should allow insurers to comply with the state external review process while the state works to correct its procedures. Requiring health insurers (and non-federal government plans) to shift their external review to the procedures in Technical Release 2011-02 or to OPM in cases where the state's non-compliance is minor (e.g., the state sets a higher than permitted charge to request an external review of an adverse benefit determination) will raise significant administrative and cost challenges for both insurers/plans and consumers.

Finally, the health insurers (and non-federal plans) should be given additional time to implement the federal procedures or to contract with HHS/OPM in states that are found to not be in compliance with the NAIC standards. If a state requests a redetermination of the initial HHS decision that the state is not in compliance, it is entirely possible that health insurers/plans and claimants will not know what review procedures to follow until October 1, 2011 which is 90

July 25, 2011

Page 12

days prior to the effective date of the Technical Release. For example, if a state is determined not to be in compliance, a health insurer in that state will need time to either establish the federal review procedures set out in Technical Release 2011-02 (including contracting with IROs) or will need to set up an agreement with OPM to conduct external reviews. This will require the insurer to establish systems for the external review, inform enrollees of the procedures, and modify health insurance policy and enrollment materials.¹⁰

Recommendations

AHIP recommends that the external review procedures and state external review approval process set for the in the Amendment and in Technical Release 2011-02 be modified to provide additional flexibility to states and health insurers:

- HHS should provide states and the public as quickly as possible with a clear statement of where states are not in conformity with the consumer protection provisions of the NAIC Model Act and what changes are necessary to the state's laws. This statement should specifically address whether the state or federal external review procedures will be applied to the individual insurance market, group insurance market, and self-funded state and local government plans.
- Health insurers and non-federal governmental plans should be permitted to continue using state external review procedures where the gaps between the state's external review law and the NAIC Model Act are minor.
- Health insurers and self-funded state and local government plans should be given additional time, until plan or policy years on or after July 1, 2012, to meet the federal standards set out in Technical Release 2011-02 or to contract with OPM to conduct external reviews if the state is found to be in non-compliance by HHS.

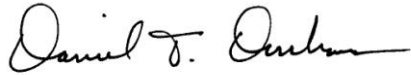
¹⁰ The need to revise policy forms and other documents is further complicated in states that require prior approval of such changes.

July 25, 2011

Page 13

AHIP and its members appreciate the efforts by the federal regulatory agencies to improve the procedures for the internal appeal and external review of adverse benefit determinations and we strongly support the changes in the Amendment to the IFR. We look forward to continuing our work on this important initiative.

Sincerely,

A handwritten signature in black ink, appearing to read "Daniel T. Durham". The signature is fluid and cursive, with a prominent initial "D".

Daniel T. Durham
Executive Vice President
Policy and Regulatory Affairs