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July 25, 2011

Attention: RIN 1210—AB45
Office of Health Plan Standards and Compliance Assistance
Employee Benefits Security Administration
U.S. Department of Labor
Room N-5653
200 Constitution Avenue, NW
Washington, DC 20210

Attention: CMS-9993-IFC2
Centers for Medicare and Medicaid Services
Office of Consumer Information and Insurance Oversight
Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Attention: REG-125592-10
CC:PA:LPD:PR (REG-125592-10)
Internal Revenue Service
Room 5205
P.O. Box 7604
Ben Franklin Station
Washington, DC 20044

Re: Group Health Plans and Health Insurance Issuers: Rules Relating to Internal Claims and Appeals and External Review Processes under the Affordable Care Act; Amendment to Interim Final Rule with Request for Comments

Dear Sir/Madam:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to provide our comments to the Department of Labor (DOL), Department of Health and Human Services (HHS), and Department of Treasury (hereafter referred to collectively as the Departments) regarding the Amendment to the Interim Final Rules for Group Health Plans and Health Insurance Issuers Relating to Internal Claims and Appeals and External Review Processes Under the Affordable Care Act (ACA)(Amended IFR).

We appreciate the Departments' willingness to respond to stakeholders' concerns raised by the original July 2010 Interim Final Rule relating to internal claims and appeals and external review processes (2010 IFR), and to allow comments on the Amended IFR. However, with respect to administrative process, given the critical importance of the appeals process for ensuring that patients receive medically necessary treatment and services as determined by their physicians, we believe that the 30-day comment period that was provided to respond to the Amended IFR, as well as to the

technical guidances (HHS Technical Guidances June 22, 2011) and technical release (DOL Technical Release 2011-02) issued contemporaneous with the publication of the IFR, is insufficient. While our initial thoughts and recommendations are provided below, we strongly urge the Departments to extend the comment period for at least an additional thirty days to enable more meaningful input.

In addition, we find it highly irregular, confusing, and improper for the Departments to issue new, substantive standards through sub-regulatory guidance, such as shortening the timeframe for filing a request for external review, which materially affect consumers' appeals rights under the ACA. At a time when the Administration is emphasizing transparency, we find this particularly egregious, and if not a violation of the Administrative Procedure Act (APA), it is certainly not in the spirit of the APA. In our view, such standards could have been—and should have been—included in the Amended IFR.

While the Amended IFR makes some needed clarifications to help patients resolve issues and disputes with their health plans, we are concerned that other changes proposed in the Amended IFR will impose barriers to patients' ability to appeal adverse benefit determinations rather than strengthening and ensuring transparency, timeliness of insurer/health plan responses, and workability of the appeals process. As we indicated in our detailed comment letter in response to the 2010 IFR (see attached September 21, 2010 comment letter), physicians are often called upon to serve as advocates for their patients and represent the first and last line of defense against arbitrary and inappropriate insurer denials of medically necessary care, treatment, and services. Given the increasing complexity of the health care system, patients, particularly those who appeal (via the internal and external processes), are often vulnerable and medically fragile. Even with the support and assistance of their physician(s), the processes for challenging an insurer's determination are daunting and require physical, financial, and emotional reserves.

We urge policymakers to strive for simplicity and policies that even the playing field between insurers and the insured. The 2010 IFR generally moved in the right direction by ensuring that the notice and review processes are transparent and unbiased. Unfortunately, we believe the Amended IFR and the accompanying sub-regulatory guidance, by scaling back several important consumer protections, moves in the wrong direction for the reasons explained below, and we urge the Departments to reverse course as noted below. We also request that the attached September 21, 2010 comment letter be considered along with these comments.

INTERNAL CLAIMS AND APPEALS

Expedited Notification of Benefit Determinations Involving Urgent Care

We are concerned that the Amended IFR lengthens the time frame in which benefit determinations must be made regarding urgent care claims. The 2010 IFR provided that a plan or issuer must notify a claimant of a benefit determination (whether adverse or not) with respect to an urgent care claim as soon as possible, taking into account the medical exigencies, but not later than 24 hours after the receipt of the claim by the plan or issuer, unless the claimant fails to provide sufficient information to enable a determination of the claim.

Under the Amended IFR, however, the period of benefit determination notification is being lengthened from 24 hours to 72 hours. While we appreciate that the IFR retains the requirement that

plans and insurers must make a determination “as soon as possible consistent with the medical exigencies involved but in no event later than 72 hours” and acknowledge the Departments’ statement in the Preamble to the Amended IFR (at 37212) that the 72-hour timeframe remains an outside limit, we support the 24-hour requirement as set forth in the 2010 IFR. At the very least, we urge that paragraph (b)(2)(ii)(B) be amended to add the Departments’ statement in the Preamble that “...the 72-hour timeframe remains only an outside limit and that, in cases where a decision must be made more quickly based on medical exigencies involved, the requirement remains that the decision should be made sooner than 72 hours after receipt of the claim.” We believe this will strengthen patient protections. We do support the language added in the Amended IFR that requires plans and issuers to defer to the attending provider’s judgment with respect to the decision whether a claim constitutes “urgent care,” and urge that this language be retained.

Additional Notice Requirements for Internal Claims and Appeals (Content)

The 2010 IFR provided additional content requirements for any notice of adverse benefit determination, including the diagnosis and treatment codes, and the corresponding meanings of these codes. In response to comments received by the Departments, the Amended IFR eliminates the requirement that notices automatically provide diagnosis and treatment codes as part of notices of adverse benefit determinations. Instead, the IFR requires that the plan or issuer provide notification of the opportunity to request these codes (and their meanings), and that the plan provide such information upon request. We are concerned this change, by adding an additional step to the process, will make it more difficult for patients to fully understand the reasons for an insurer’s adverse determination, and add unnecessary delay to the appeal process, which is even more critical since the IFR also shortens the timeframe that patients have to bring appeals (see discussion below). We recommend this change be reversed.

If the Departments maintain this change, however, we urge that the text of the IFR be amended to specifically require plans, if requested by the patient, to provide the diagnosis and treatment codes in writing, along with an easily understood narrative statement of the codes’ meanings, rather than just a summary explanation such as “not medically necessary” or “experimental/investigational.” The plan should be required to explain the actual reasons why a treatment or service is not medically necessary and provide the standards and actual clinical criteria used to support such a determination. This information will help the patient in making an informed judgment on whether to appeal an adverse determination, and provide necessary background to make any such appeal meaningful and successful.

EXTERNAL REVIEW

Transition Period for State External Review Processes and Timeframe for Filing a Request for External Review

Under the 2010 IFR, states were given a transition period to adopt the broader and more uniform federal minimum standards required by the ACA. The IFR, as well as subsequently-issued agency guidance, provided that if existing state external appeal laws did not meet the minimum consumer protections of the National Association of Insurance Commissioners (NAIC) Uniform Model Act (NAIC Model), insurance coverage would be subject to external review process requirements under

federal standards under the NAIC Model. A transition period was provided until July 1, 2011 for states to have time to amend their laws to meet or go beyond the minimum consumer protections of the NAIC Model. The Amended IFR provides an additional six months, until December 31, 2011, for this transition process to allow states more time to complete this process.

While we understand the need to be flexible on the transition process given the realities of different state legislative calendars, we are concerned that the Departments have chosen to scale back some of the consumer protections that were required in the 2010 IFR. According to the DOL Technical Release, states may also choose to apply a set of temporary standards under federal standards that are similar to the NAIC Model until January 1, 2014. We are particularly concerned about a change in the timeframe that claimants have to file a request for external review. Under the temporary standards, a claimant has only 60 days to file such a request after receiving notice of an adverse benefit determination, rather than 120 days as provided in the 2010 IFR. We do not believe that this shortened timeframe allows sufficient time for individuals to gather all of their relevant documentation, such as medical records and physician letters, and prepare for their appeal.

Moreover, while there is a general reference in the Preamble to the Amended IFR about these temporary NAIC-similar standards, there is no specific explanation or discussion in either the DOL Technical Release or in the Preamble to the Amended IFR of why these particular standards were scaled back, nor do these revised standards appear anywhere in the actual text of the IFR. These changes seem arbitrary and we believe they seriously undercut the intent of the ACA's appeals provisions to provide consumers with enhanced protections and a uniform framework for external review of insurance coverage decisions. As mentioned previously, we also believe making such substantive changes through sub-regulatory guidance may violate the APA.

Choice of IROs—Conflict of Interest

For self-insured health plans subject to ERISA or the Internal Revenue Code, a federal external review process supervised by the DOL and Treasury applies (referred to as the private accredited Independent Review Organization, or IRO, process). Under guidance issued in 2010, the DOL provided an interim enforcement safe harbor for self-insured plans, if they voluntarily complied with a state external review process or complied with certain standards set forth in the Technical Release, one of which permits plans to contract with accredited IROs to perform reviews. Under DOL Technical Release 2011-02, this process was amended to allow plans to be eligible for a safe harbor if they contract with at least two IROs by January 1, 2012, and with at least three IROs by July 1, 2012, and rotate assignments among them. We believe that allowing plans to choose the IRO presents a conflict of interest that undercuts the intended protections provided by the ACA. We note that one of the minimum consumer standards of the NAIC Model provides that “the IRO must be assigned by the state or an independent entity, on a random basis or another method of assignment that ensures the independence and impartiality of the assignment process (such as rotational assignment), and in no event assigned by the issuer, the plan, or the individual.” We urge that DOL and Treasury apply this more stringent standard rather than allowing plans to have their choice of IROs.

We are also concerned that the timeframe in which an IRO must inform a claimant of its decision has been changed. According to the DOL Technical Release, an IRO will have 60 days, rather than 45 days, to inform a claimant in writing of its decision on an external review request. As with the

timeframe for filing a request for external review, there is no explanation as to why this change is being made, nor does the text of the Amended IFR include this language.

Scope of Claims Available Under the Federal External Review Process

We are troubled that the Amended IFR narrows the scope of claims eligible for external review under the federal external review process. We strongly supported the scope included in the 2010 IFR, which provided that any adverse benefit determination could be reviewed unless it related to an enrollee's failure to meet eligibility requirements under a group health plan. Under the Amended IFR, however, this scope has been narrowed to allow only review of claims involving: 1) medical judgment, excluding those that involve only contractual or legal interpretation without any use of medical judgment, as determined by the external reviewer; or (2) a rescission of coverage. While we are pleased that both medical judgment and rescission of coverage have been retained, we urge the Departments to go back to the original scope of review. It will be difficult in many cases to determine whether billing and coding errors or failure to obtain pre-authorization involve "medical judgment," as opposed to contractual or legal interpretation, which will only delay the review process. Moreover, it is not clear whether the external reviewer's decision as to whether an issue involves medical judgment will be appealable.

As the Preamble to the Amended IFR noted in summarizing comments to the 2010 IFR, consumers with self-insured health plans have almost no effective means of enforcing their contractual claims and rights to benefits through traditional ERISA enforcement. We believe that the scope of claims eligible for the federal external process should be as broad as possible to level the playing field of claims adjudication.

Clarification Regarding Requirement That External Review Decision is Binding

We strongly support the clarification in the Amended IFR that a plan must provide benefits or pay a claim without delay, pursuant to a final decision by an IRO, even if the plan is going to seek judicial review. We agree with the Departments that the binding nature of the IRO's decision should not preclude the plan from acting in accordance with the IRO's decision, unless or until there is a judicial decision otherwise.

FORM AND MANNER OF NOTICES (LANGUAGE ACCESS)

The ACA requires group health plans and health insurance issuers to provide relevant notices in connection with internal claims and appeals and external review processes in a culturally and linguistically appropriate manner. The 2010 IFR mandated the provision of culturally and linguistically appropriate notice(s) that include the relevant information needed to understand what claim(s) have been denied and the basis of the denial in addition to the recourse available to the insured. We supported these requirements, which required that notices be provided in a non-English language based on certain thresholds of the number of people in the plan who are literate in the same non-English language. The complexity of the appeals and external review process poses a significant barrier for many patients and consumers. This is particularly true when there are language barriers.

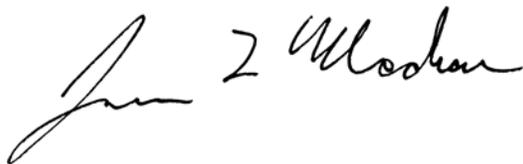
The Amended IFR, however, changes the threshold determination from the number of non-English language enrollees in a plan to the number of such residents in the claimant's county. We do not believe that this change is appropriate because in many cases county demographics may differ from a plan's demographics. Some plans may market specifically to certain non-English language groups, while others may not, which may skew the results in applying the thresholds. We are concerned this may result in inadequate translation of written communications into non-English languages, which will prevent non-English speaking enrollees from understanding their legal rights and the processes to follow for claim review and appeals.

While we appreciate that the Departments were trying to balance the goal of protecting consumers by providing understandable notices to individuals who speak primary languages other than English against the goal of simplifying burdens on plans and insurers, we believe the changes to the language-access provisions in the Amended IFR will weaken consumer protections. We are particularly concerned that oral interpreter assistance should be provided to all non-English language enrollees, rather than only when the thresholds set forth in the accompanying guidance document are met.

CONCLUSION

We appreciate the opportunity to provide comments and look forward to working with the Departments to protect consumers' and patients' access to medically-necessary care, as determined by their physicians. We urge the Departments to make changes, as discussed above, to the Amended IFR to ensure that the appeals process is transparent and streamlined, and evens the playing field between patients and insurers.

Sincerely,

A handwritten signature in black ink, appearing to read "James L. Madara". The signature is written in a cursive style with a large, stylized initial "J".

James L. Madara, MD

Attachment



Michael D. Maves, MD, MBA, Executive Vice President, CEO

September 21, 2010

Attention: RIN 1210—AB45
Office of Health Plan Standards and Compliance Assistance
Employee Benefits Security Administration
U.S. Department of Labor
Room N-5653
200 Constitution Avenue, NW
Washington, DC 20210

Attention: OCIO-9993-IFC
Office of Consumer Information and Insurance Oversight
Department of Health and Human Services
Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Attention: REG-125592-10
CC:PA:LPD:PR (REG-125592-10)
Internal Revenue Service
Room 5205
P.O. Box 7604
Ben Franklin Station
Washington, DC 20044

Re: 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

Dear Sir/Madam:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to provide our comments regarding 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 (IFR). While overall we strongly support provisions of the IFR that are consistent with congressional intent and place patients and consumers first, we have both specific and general concerns and recommendations.

In general, physicians are often called upon to serve as advocates for their patients and represent the first and last line of defense against arbitrary and inappropriate insurer denials of medically necessary care, treatment, and services. Given the increasing complexity of the health care system, patients, particularly those who appeal (via the internal and external processes), are often vulnerable and medically fragile. Even with the support and assistance of their physician(s), the processes for challenging an insurer determination are daunting and requires physical, financial, and emotional reserves. We urge policymakers to strive for simplicity and policies that even the playing field between insurers and the insured. We believe, for the most part, the IFR moves in the right direction by ensuring that the notice and review processes are transparent and unbiased.

Clinical Integrity of Medical Decision-Making

The AMA urges the Departments to modify the IFR language and include explicit new language that ensures that the clinical integrity of medical decision-making is protected as part of the appeals process. No amount of notice or process will result in an appropriate clinical outcome if the underlying standards are not clinically appropriate, or the reviewers are not qualified to make decisions concerning the clinical issues at stake.

The AMA has adopted a Health Insurer Code of Conduct, governing both clinical and business operations of health plans, which the medical profession has found to be critical to the delivery of efficient, patient-centered health care. These principles put the patient's best interests first. Of the Code of Conduct's 10 clear principles, two of the principles directly address the need to protect the clinical integrity of medical decision-making. The relevant principles provide:

Medical Necessity

- Medical care is “necessary” when a prudent physician would provide it to a patient for the purpose of preventing, diagnosing or treating an illness, injury, disease or its symptoms in a manner that is: (a) in accordance with generally accepted standards of medical practice; (b) clinically appropriate in terms of type, frequency, extent, site and duration; and (c) not primarily for the economic benefit of the health plans and purchasers or for the convenience of the patient, treating physician, or other health care provider.
- All emergency screening and treatment services (as defined by the prudent layperson standard) provided by physicians and hospitals to patients must be covered without regard to prior authorization or the treating physician's or other health care provider's contractual relationship with the payer.
- Health insurers must not use financial incentives that discourage the rendering, recommending, prescribing of, or referral for medically-necessary care.
- No care may be denied on the grounds it is not “medically necessary” except by a physician qualified by education, training and expertise to evaluate the specific clinical issues.

- Patients and their physicians must have the right to a transparent appeal process and obtain a free, timely, external review of any adverse benefit decision based on “medical necessity” or a claim the service is “investigational” or “experimental.”

Benefit Management

- Clear information on benefit restrictions must be readily available to patients and physicians.
- Decisions based on formularies or other benefit management tools must be consistent with clinically appropriate medical guidelines, and physicians must have a simple, fast way to get exceptions when warranted by their patients’ medical needs.
- Adverse changes to formularies or other benefits must not be made during the plan coverage year, and physicians who have stabilized a patient on a particular medication or other treatment regime must not be forced to change those medications or other treatments, nor should these patients be required to incur additional costs based upon such changes.
- Financial incentives must not corrupt benefit decisions, and all financial incentives potentially impacting benefit decisions must be fully disclosed.

The notice requirements and many other provisions of the internal and external appeals process proposed in the IFR go a long way toward achieving many of the above process criteria. As a result, we strongly support these patient and consumer protections embodied by the IFR.

Nevertheless, the IFR does not contain the necessary safeguards to ensure that the tests used by insurers to determine whether a treatment is “medically necessary” or “experimental or investigational” are clinically appropriate, or that the individuals who are applying those tests are clinically qualified. To the contrary, the IFR contains proposed regulatory language that will gut the strong protections contained in the proposed framework unless modified and amended. Specifically, on page 43356, under (c)(iii)(2)(i), the IFR provides that:

[t]he State process must provide for the external review of adverse benefit determinations (including final internal adverse benefit determinations that are **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.

(Emphasis added.) To the extent that an insurer/plan does not require definitions that are appropriate, no amount of notice or process will result in an appropriate clinical outcome. At the state level, this phenomenon has been addressed through the adoption of baseline definitions and rules that protect the clinical integrity of medical decision-making. **We strongly urge the Departments to adopt the same or similar mandatory definitions and rules below as part of the required elements of state and federal processes:**

- Definition of “clinical criteria and utilization review protocols.” “Clinical criteria and utilization review protocols” means the written policies, written screening procedures, drug formularies or lists of covered drugs, decision rules, decision abstracts, clinical protocols, practice guidelines, medical protocols used by the Insurer/Plan to determine the necessity and appropriateness of health care services.
- Basis of clinical criteria. “Clinical criteria and utilization review protocols” must: be based on nationally-recognized standards; be developed in accordance with the current standards of national accreditation entities; reflect community standards of care; ensure quality of care and access to needed health care services. Clinical criteria must, if practicable, be evidence-based. Clinical criteria and utilization review protocols must be sufficiently flexible to allow deviations from norms when justified on case-by-case bases.
- Lack of evidence-based standards. If no independently-developed evidence-based standards exist for a particular treatment, testing, or imaging procedures, Insurer/Plan will not deny coverage of the treatment, testing, or imaging procedures based solely on the grounds that the treatment, testing, or imaging does not meet an evidence-based standard.
- Basis of utilization review determinations. All utilization review determinations made by the Insurer/Plan must be based on written clinical criteria.
- Physician role in clinical criteria development. Prior to establishing, or substantially or materially altering, clinical criteria and review protocols, Insurer/Plan will obtain input from actively practicing physicians within the Insurer/Plan’s provider network and within the Insurer/Plan’s service area. Such physicians must represent major areas of specialty and be certified by the boards of the various American medical specialties. The Insurer/Plan will seek input from physicians who are not employees of the Insurer/Plan, or consultants to the Insurer/Plan if the physician is a consultant only for the purpose of developing clinical criteria and utilization review protocols.
- Obligation to update. Insurer/Plan will periodically review and update its clinical criteria and protocols and maintain evidence of such periodic reviews. Clinical criteria and utilization review protocols must be updated at least biennially and as new treatments, applications, and technologies.

The foregoing definitions and rules are essential to medical decision-making that is grounded in clinical integrity as opposed to considerations such as costs, profits, and administrative convenience.

INTERNAL CLAIMS AND APPEALS

With respect to internal claims and appeals processes for **individual health insurance coverage**, we support the IFR provision mandating that all of the **group health coverage requirements** discussed below will apply to the internal claims and appeals process for individual health

coverage. We also support the additional three requirements that protect consumers in the individual market, including: (1) expanding the appeals process to cover initial eligibility determination; (2) abolishing any second-level review; and (3) the specific documentation requirements.

As noted in the IFR, the internal claims and appeals processes for **group health coverage** (plans and issuers) must initially incorporate the internal claims and appeals processes set forth in 29 CFR 2560.503-1 and update such processes in accordance with standards established by the Secretary of the U.S. Department of Labor (DOL).

We applaud and strongly support the additional six supplemental IFR requirements, including those that:

- expand the definition of adverse benefit determination(s) to include, among other things, rescission of coverage;
- shorten the period of benefit determination notification from 72 hours to 24 hours;
- require insurers and plans to provide, free of charge, any new or additional evidence considered, relied upon or generated in advance of a notification of determination;
- ensure the impartiality of the persons involved in decision-making including a bar on bonuses based on denials; and
- mandate the provision of culturally and linguistically appropriate notice(s) that include the relevant information needed to understand what claim(s) have been denied and the basis of the denial in addition to the recourse available to the insured.

We also strongly support the proposal to issue a model notice that would satisfy all of the requirements under this IFR. While the actual content of the notices is important, **equally important is the organization of the notice, the use of font and other formatting techniques, as well as issues related to comprehension.** Physicians and their staff often must read these notices and to the extent there is uniformity, it will decrease time expended to find the relevant information and reduce confusion.

Finally, we would welcome the opportunity to work on a Health Insurance Portability and Accountability Act standard for an electronic appeals process, as we believe there is a tremendous opportunity for streamlining appeals through such a standard.

EXTERNAL REVIEW

With respect to external review, the law establishes a process for determining whether a State external review process or a Federal external review process applies. While we are, generally, greatly encouraged and pleased by the IFR provisions concerning external reviews, we strongly recommend the addition of several elements that are minimally necessary to protect consumers.

In addition, we recommend modification of proposed language and the inclusion of definitions and baseline rules that protect the integrity of clinical decision-making.

Conflicts of Interests

We strongly support the elements identified as the minimum consumer protections that must be a part of a State external review process that were drawn from the Uniform Health Carrier External Review Model Act promulgated by the National Association of Insurance Commissioners (NAIC Model Act). In particular, we applaud those elements that prohibit insurers from having a role in the selection or payment of Independent Review Organizations (IRO). We support the additional elements that ensure the IROs do not have a conflict of interest and remain independent and viable (even where they make determinations adverse to insurers).

Evidence-Based Standards and Best Evidence

We strongly urge the Departments to clarify and expand upon the appropriate use of evidence-based standards for the State and Federal appeals process, as well as the definition of best evidence. The following suggested changes should be added as elements that represent essential consumer protections. We are extremely concerned that the omission of these clarifying elements will seriously undermine the ability of physicians to provide patient-centered care that reflects medical necessity and quality care. The AMA has vigorously supported efforts to increase the evidence base of medicine and has been a vocal advocate of comparative clinical effectiveness research, for example. While we are very aware that evidence-based medicine, when properly translated and applied to practice, has the potential to enhance care, we are equally and acutely aware that the evidence-based standards can be misused or developed without the requisite emphasis on clinical considerations or without proper consideration of variations within communities and among individuals. In short, without proper precaution, standards could be fashioned to represent “evidence-based medicine,” but may in practice be highly detrimental to certain individual patients or categories of patients. As a result, we strongly urge the addition of the following new elements.

We recommend that the Departments include an element that requires that the review of adverse determinations of medical necessity will be based on whether the case involved health care services or products that a prudent physician would provide to a patient for the purpose of preventing, diagnosing, or treating an illness, injury, disease or its symptoms in a manner that is:

- (a) in accordance with generally-accepted standards of medical practice;
- (b) clinically appropriate in terms of type, frequency, extent, site and duration; and,
- (c) not primarily for the economic benefit of the health plans and purchasers or for the convenience of the patient, treating physician, or other health care provider.

We urge adoption of additional language that provides further that “generally-accepted standards of medical practice” means “standards that are based on credible scientific evidence published in peer-reviewed medical literature generally-recognized by the relevant medical community, physician specialty society recommendations and the views of physicians practicing in the relevant clinical areas and any other relevant factors.” This is essentially the definition of “medical necessity,” which is incorporated in the AMA’s Health Insurer Code of Conduct, and was adopted in multi-district litigation settlements with some of the largest health plans in the country. Inflexibly limiting reviews to “evidence-based standards” without accounting for the factors above undermines the delivery of patient-centered care (and could actually exacerbate health disparities). Furthermore, the rigid application of “evidence-based” standards is questionable when the “evidence” on which they are based consists primarily of actuarial assumptions rather than medically-based standards of care.

We also urge the Departments to include an element that clarifies that the best evidence used in the appeals process afford appropriate weight and deference to expert opinion, including that of the treating physician. To do otherwise could open the door to conferring disproportionate weight on insufficiently qualified non-physician individuals who do not have all the relevant information and have not examined the patient.

It is also essential that the clinical integrity of the medical decision-making process be protected throughout internal and external appeals. To ensure that the integrity of these decisions is ensured, the definitions of “medical necessity,” “experimental,” and “investigational” must be medically appropriate.

Moreover, the individuals who make utilization review decisions must be clinically qualified to do so by professional education, training, licensure, and experience specific to the medical issue in question. One way to ensure that the IRO reviewers focus on the patient's best interest would be to mandate the questions that they must answer along the following lines:

The expert reviewers shall be instructed by the IRO to answer the three questions listed below. No other questions shall be posed to the expert reviewers.

- a) Is the requested therapy likely to be more beneficial for the enrollee than that authorized by the plan? List the reasons that the therapy should or should not be provided by the plan, citing the enrollee’s specific medical condition, the relevant documents provided, and the relevant medical and scientific evidence;
- b) Are the medical records and accompanying information sufficient to answer the question noted above? If not, please notify <NAME OF IRO> immediately of the additional information required; and
- c) Is there any other treatment not under consideration that can reasonably be expected to be more beneficial for the patient?

This would ensure that the patient's welfare is the focus of the inquiry, and only the medically-relevant issues to the patient's welfare are considered.

Application of Federal Process v. State Process

The AMA supports application of the federal external review process to all plans and issuers in a state only if: (1) there does not exist an applicable state external review process that meets the prescribed requirements and elements laid out in the IFR (as modified by our recommended changes) or (2) the state external review process does not apply to all issuers/plans and the consumer protections are not as stringent as those laid out in federal law. We generally would not support superseding state laws that provide a higher level of consumer protection even though the standards/requirements among insurers/plans would vary.

Nationally-Accredited Entities

While we support mechanisms such as accreditation that would ensure the quality and independence of IRO services, we do not support the uncertainty created by not defining which national private accrediting entities will be recognized as IRO accreditors.

We also strongly urge the inclusion of another element that provides that the treatment decisions or recommendations by physicians must be reviewed only by IRO experts who are actively practicing physicians familiar with the medical condition or treatment in question, of the same specialty, and licensed and actively practicing in the same state where the treating physician is practicing. If out-of-state review entities contract with physician reviewers who are not practicing within the same state as the treating physician, it will weaken the use of relevant, case-specific information by equivalently qualified peer physicians. Furthermore, the Departments should require that any changes in the standards for IRO accreditation by the accrediting entity, must be reviewed and approved by the relevant state insurance commissioners or NAIC where they are authorized to confer accreditation.

NOTICES

We strongly support the IFR setting forth the form and manner of providing **notices** in connection with internal claims and appeals and external review processes. The complexity of the appeals and external review process is a significant barrier for many patients and consumers. This is all the more true when there are language barriers. The notice provisions will ensure that patients/consumers will receive notice and understand the nature of their rights and deadlines.

CONCLUSION

We appreciate the opportunity to provide comments and look forward to working with the agencies to protect consumers and patients access to medically-necessary care. It is essential that

U.S. Department of Labor
Department of Health and Human Services
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Page 9

the appeals process is simplified, streamlined, and evens the playing field between consumers/patients and insurers.

Sincerely,

A handwritten signature in black ink that reads "Mike Maves". The signature is written in a cursive, flowing style.

Michael D. Maves, MD, MBA