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September 21, 2010

Submitted via the Federal eRulemaking Portal **http://www.regulations.gov**

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

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

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

Dear Sir or Madam:

Magellan Health Services (Magellan) welcomes the chance to comment on the Interim Final Rules for Group Health Plans and Health Insurance Issuers Relating to Internal Claims and Appeals and External Review Processes Under the Patient Protection and Affordable Care Act (IFR). Magellan Health Services is one of the largest specialty carve-out organizations in the country. As a carve-out organization, we are responsible for the administration of the specialty health benefits provided by our customers to group and individual health plan members. Magellan customers include both health plans and employers, covering millions of members nationwide. We have concerns with several requirements in this regulation as it is currently written.

Inclusion of Diagnosis Code in the Notices

We would encourage you to remove the requirement to include the diagnosis code in the denial notifications. Section 2719 of the Patient Protection and Affordable Care Act (PPACA) did not require this element. As a company that provides utilization management services for substance abuse, mental health and oncology conditions, we have a number of concerns with including information of this sensitive nature in the correspondence.

First, we have a clinical concern: Viewing a diagnosis on their benefit correspondence that indicates screening for a type of cancer, or a behavioral health diagnosis like bipolar disorder or alcoholism, could be upsetting to the patient. Providers may, for appropriate clinical or other reasons, not clearly disclose the diagnosis to the patient. Disclosure of a diagnosis by the plan may not only cause distress to the patient; in some instances, it may interfere with the doctor-patient relationship. Plans should not be the first to disclose diagnoses to patients. While current denial letters may contain a significant amount of clinical information, they do stop short of labeling the member as an alcoholic or in most cases identifying someone as an individual with a particular type of cancer.

Second, inclusion of such sensitive protected health information (PHI) increases the risk of potential harm to the patient if a denial notice or explanation of benefits is inadvertently misdirected. And, patients with especially sensitive diagnoses, such as substance abuse or cancer, will again sustain distress when notified pursuant to HITECH of an inadvertent disclosure through misdirected correspondence.

Third, plans and managed care companies do not actually diagnose the member; we only receive information about diagnosis from the caller (usually the provider or the facility). Many times, at the time of admission or of the initial call, the facility or provider has not yet seen the patient and is unable to furnish a diagnosis code; as a result, the managed care organization would not have a diagnosis to include in the correspondence. In addition, a URAC standard for Health Care Utilization Management (HUM 26) prohibits managed care organizations from requiring providers requesting pre-certification of a benefit to furnish numerical code procedures or diagnoses; as a result, codes will not be available for inclusion in letters regarding a significant number of claims for benefits.

In addition, diagnosis is not generally a material element in our decision-making; our denials are based on the severity and intensity of symptoms and behaviors in relation to a specific procedure/service and are not necessarily related to a diagnosis. Moreover, behavioral health diagnoses frequently change between levels of care and even within an episode of care. The admission diagnosis to an inpatient facility is often very different from the discharge diagnosis; the discharge diagnosis is often different from the diagnosis submitted by the outpatient provider who follows the case. Seeing multiple diagnoses will just add confusion for such patients.

Fourth, the inclusion of diagnosis unnecessarily increases the sensitive PHI that circulates about patients both within and outside of the managed care organization. While diagnosis may not be an issue for many conditions, most people are particularly sensitive to disclosure of behavioral health and cancer diagnoses. There is no reason for claims processors to know diagnoses, yet

this requirement would expose all claims processors to diagnosis information, contrary to the expectations of the regulations under HIPAA. Similarly, administrators for flexible spending plans have no need to know diagnoses; EOBs that detail behavioral health diagnoses may discourage plan members from submitting claims to the flexible spending plan administrator for reimbursement. In addition family members opening mail sent to the household might see such diagnoses with untoward consequences for the member.

We encourage you to require only that information necessary to enable members to identify the claim being denied and leave it to plan discretion to determine what and how much information needs to be disclosed, so long as plans furnish sufficient information to reasonably identify the specific claim being denied.

Model Notices and Letter Requirements

We appreciate the department issuing model notices and see value in having these available for plan use. We would suggest that the notices be revised and re-issued to include the following additional elements that are required by accreditation agencies (e.g., URAC and NCQA) or the existing ERISA claims regulation. Most utilization review entities hold these accreditations and will have to edit these elements into the model notices.

Model Notice of Adverse Benefit Determination -- add the provider's right to a peer-to-peer discussion;

Model Notice of Final Internal Adverse Benefit Determination -- add the reviewer's title and qualifications;

All model notices -- add the right to obtain the benefit provision or guideline used in the decision process free of charge to the explanation section (existing ERISA requirement);

All model notices -- add the timeframe to request the appeal and the turnaround time for a standard appeal; and

All model notices -- add a placeholder for information that the claimant may provide to 'perfect the claim' (existing ERISA requirement).

In addition, some of the requirements listed in the IFR appear to be repetitive of elements already contained in the ERISA claims regulation in § 2560.503-1(g) and (j). We would like some clarification on whether or not there is actually additional information required and, if so, what it is. For example:

> §2590.715-2719 (b)(2)(ii)(E)(2) requires a description of the standard used in denying the claim. Given that §2560.503-1(g)(iv) already requires plans to furnish any internal rule, guideline, protocol, or other similar criterion was relied upon in making the adverse determination, it is not clear what additional information is expected by the IFR requirement.

§2590.715-2719 (b)(2)(ii)(E)(2) requires a discussion of the adverse determination decision. It is not clear what is left for plans to discuss given the detailed requirements under the combined rules that plans furnish the specific reason(s) for the adverse benefit determination, the meanings of codes, the standard and internal rule, guideline, protocol, or other similar criterion applied, a description of information or materials that would perfect the claim along with an explanation of the need for that information or materials, identification of the applicable plan provision, and, as applicable, an explanation of the scientific or clinical judgment applied to the claimant's circumstances.

§2590.715-2719 (b)(2)(ii)(E)(3) requires a description of available internal appeals and external review processes, including information regarding how to initiate an appeal. Other than adding notice of the external review processes, it is not clear what additional information is expected in the requirement given that a description of the review procedures, the applicable time limits, and a statement of the right to sue under ERISA is already required in §2560.503-1(g) (iv).

If the Departments' intent was to set forth additional requirements with respect to the duplicative provisions, clarification of the intended meaning would enable plans to comply. If instead, the Departments' intent was only to amplify existing requirements, integration of the two sets of regulations and/or clarification of terms would eliminate the ambiguity resulting from the overlap.

We would also like some clarification on whether or not the Departments plan to release another version of these notices in the near future after comments are considered; it would be helpful for us to know that before we modify 1000's of letter templates to conform to the model notices.

Application to Employee Assistance Programs

Employee assistance programs (EAPs) that may be considered to be employee welfare plans under ERISA should not be required to comply with the IFR requirements, at least to the extent that they supplement group health plans.[1] PPACA's focus is health benefit plans and arrangements for them. EAPs are not true health benefit plans. While it is true that some health care services are provided by EAPs and that employers purchase those services for their employees, that is the end of the resemblance to health benefit plans. Employee eligibility for EAP services is automatic; EAPs do not require enrollment or employee contribution to premium. EAPs rarely receive eligibility data from employers and rarely screen for eligibility. Unlike true health benefit plans, EAPs typically make services available to anyone who happens to share an employee's household at the time services are requested and rely on self-report to establish the asserted relationship of a claimant to a covered employee. In contrast to health benefit plans, which may try to control costs by managing utilization, EAPs constantly strive to promote greater utilization in order to prove their value to employers; as result, adverse determinations rarely occur.

Neither employers nor employees typically consider EAPs to be health benefits. The services provided under EAPs are much broader than health services. Traditional EAPs provide members

[1] The same considerations apply also to the application of §2560.503-1 to EAPs.

problem assessment and counseling services for day-to-day problems that extend well beyond health issues – for example, work-related issues, parenting concerns, and grief -- in addition to assessment and counseling for emotional issues and assessment of substance abuse. Many EAPs also furnish members legal consultation services, financial consultation services, services related to child care and elder care, convenience services (e.g., locating a plumber, travel arrangements, etc.)

EAPs are not intended to be health benefit plans. Instead, EAPs are workplace-based programs designed to help employers and unions enhance workplace productivity, safety, and culture by helping employees and their household members address personal problems. The focus of EAPs is on promoting workplace productivity and safety, not the health of employees; in addition to services for employees and their household members, EAPs typically perform an array of services that relate more to human resource management than health care, e.g., consultation to supervisors on managing employees with disruptive workplace behavior or productivity lapses, support of employer drug-free workplace initiatives, and critical incident management. EAPs frequently work alongside management in planning lay-offs and response structures for threats of violence and similar management concerns. Some employers provide EAP services to permit them to conduct employee drug testing under applicable state law; others make EAP services available to better ensure safety in hazardous workplace environments.

Because employees make no financial contribution, they are not in need of legal protections to ensure they get value for their money. But the costs of applying the requirements to EAPs are high.

> EAP fees to employers are very low relative to the medical and administrative costs of health benefit plans. For EAPs, the additional expenses associated with compliance are inordinately high; for an EAP of a small employer, the compliance cost associated with just one appeal could outweigh the cost of the EAP itself. That is an unreasonable burden.
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> The requirements for notice of adverse benefit determinations run counter to EAP commitments regarding confidentiality. To encourage use of the EAP to resolve problems, particularly by individuals who may resist seeking mental health treatment under their health plan due to stigma, EAPs have consistently promised the highest standards of confidentiality, including refraining from calling EAP members or sending mail to EAP members unless they explicitly permit such communications. The regulations require written or electronic communication of all adverse benefit determinations without consideration of member privacy concerns. Requiring EAPs to send written or electronic notices would undermine confidentiality expectations, particularly if diagnoses are included, and would deter some employees and household members from accessing EAP services.
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> Many of the items required to be present in notices are irrelevant to EAPs; requiring EAPs to furnish compliant notices would impose unnecessary busy work on EAPs to establish systems to collect, record, and retrieve information that has little or no bearing on EAP services and the few adverse determinations that may occur. Because they are

not used and/or are rarely relevant to adverse determinations, the following information has little, if any, meaning for EAP claim determinations:
Diagnosis codes and their meanings;
Procedure codes and their meanings,
Denial codes and their meanings;
ID numbers;
References to medical necessity

Given the minimal overlap between EAPs and health benefit plans, along with the imbalance between benefits and costs in applying the requirements to EAPs, we request that the Departments exempt EAPs from some or all of the claims, appeals, and external review requirements. At minimum, if the Departments choose not to exempt EAPs, we respectfully suggest they add an option for EAPs to furnish oral notice only with documentation of an EAP member's preference and that they establish a process to approve alternative forms of notices that would be more appropriate for EAPs.

Individual Plan Internal Appeal Process

The langauge in the IFR that restricts individual plans to only one level of internal appeal will create process issues for large insurers that currently handle both their group and individual membership through the same two-level appeal process. The comments note that this one-level process is required because "There is no need for a second level of an internal appeal in the individual market since the issuer conducts all levels of the internal appeal". While the same entity may conduct both levels of review, our process (and that of most of our customers) for medical necessity reviews is to use independent reviewers with no prior knowledge of the case to conduct each level of the review process. Having an independent reviewer evaluate the case does provide an opportunity for an unbiased and fair review and should be permitted for individual plans. We conduct specialty reviews for numerous insurers that include individual members in the business that we manage. Under these regulations, we will have to create new processes to identify these individual members so that we can limit them to one review, creating additional administrative work for us and the health plans while removing a level of review with the potential to benefit the members. We encourage the Departments to allow insurers the same discretion to offer one or two appeal levels as are available to group plans.

Verbal Notification

Given the expansion of information required in notices, plans should not be required to include all of the information in 29 CFR 2590.715-2719(b)(2)(ii)(E) and §2560.503-1(g)(1) in oral notices furnished under §2560.503-1(g)(2). Because some of the required information, such as procedure code, may not be readily available at the time of the initial pre-authorization call, the requirement would mandate follow-up telephone calls to communicate full information. Moreover, it is likely that health care providers will not want to spend the additional time in prolonged -- or follow-up -- telephone calls needed to communicate all of the information required by the IFR. Instead of mandating that all of the listed information be provided proactively in oral notices, we suggest that plans be required only to proactively furnish in oral notices the reason for denial and a description of the process for expedited appeal, with an offer to furnish the remainder of the items on request.

We also request that the Department of Labor amend the regulation to permit verbal notification for the initial communication of urgent pre-service appeal determinations in section 2560.503-1(i)(2)(i) or 2560.503-1 (j) to be followed with the written communication. Doing so would allow a consistent process for handling expedited requests throughout the internal process and allow us to provide a more timely response to the claimants in these reviews.

Written Notification

We also ask that you reconsider the timeframe for the provision of written notification for urgent care claims and urgent care appeals when the oral notice has been provided timely. The current standards for initial urgent care reviews require that the notice be furnished to the claimant within 3 days of the oral notification. With the postal service considering elimination of Saturday delivery, ensuring that the notice reaches the member in this timeframe may be impossible for Friday reviews. In addition, with the new translation standards, sending a letter out for translation will add time to the notification process and make meeting this timeframe impossible. If the oral notification is given timely and includes appeal rights, there should be less urgency in the written correspondence getting to the claimant. We would suggest a standard in business days and calculated based on the date the letter is mailed since it is virtually impossible to know how many days it will take for a letter to be received by an individual when it is sent through the mail.

Strict Liability Standard

We would urge you to reconsider the standard that states that a claimant will be deemed to have exhausted the internal claims and appeals process regardless of whether the plan or issuer asserts that it substantially complied with the requirements of the regulation or that any error committed was de minimis. This will permit members in all cases with even minor harmless error to pursue remedies under ERISA, including a civil lawsuit. This could increase litigation costs for plans at a time where costs are escalating and plans and employers are struggling to rein in costs. We would ask that you allow plans to have an opportunity to cure de minimis mistakes rather than members automatically having a right to proceed to external review and civil lawsuit.

Effective Date

The compliance date of on or after September 23, 2010 for plans that are new or renewing is a very aggressive compliance deadline that is likely impossible for many insurers and managed care organizations to meet. Large insurers and managed care organizations with business in all 50 states need to evaluate these changes to correspondence and process and re-program IT systems with changes. Model notices were released on August 23, 2010, which only gave plans a month to evaluate the possible use of these notices and to incorporate necessary elements for their use. State law elements will need to remain in the correspondence as will customer-specific requirements and any additional ombudsman information for states that previously did not require this information to be included in the letters. Changes are also necessary for translation of initial letters and IT systems to flag when continuing correspondence will be required in a foreign language. Adding to this complexity, some employer groups are still determining if they will assert grandfathered status, which necessarily delays implementation of any compliance

efforts for those plans until this determination is made. We were pleased to see the Department of Labor Technical Release 2010-02 that was released yesterday which addresses these concerns. We would like to see this document clarified to indicate that the enforcement grace period applies to all plans that are subject to the IFR. The current langauge is unclear with regard to several plan types including fully insured plans (group and individual) that are subject to the HHS interim external review process that is administered by OPM and to self-funded federal government plans.

We appreciate the opportunity to comment on these regulations. If you would like further information on any of the issues raised in this letter please feel free to contact me at 410-953-4710 or tmberman@magellanhealth.com.

Sincerely,

Teresa Berman
Senior Legal Counsel
Magellan Health Services