Humana Inc.
1100 Employers Blvd.
Green Bay, WI 54344
800 558 4444 Tel
www.humana.com

#3

December 4, 2008

Bonnie L. Harkless
Room C4-26-05
Division of Regulations Development
Office of Strategic Operations and Regulatory Affairs
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

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Guidance when you need it most

Dear Ms. Harkless:

Thank you for the opportunity to respond to the draft of the 2010 Plan Benefit Package (PBP) and Formulary Submissions documents.

We would like to submit the following comments and question for consideration regarding the Draft 2010 Formulary submission screens.

- **Part D**

Regarding the Medicare Prescription Drugs Section screens, there is one field where the explanation (located in the box that appears under this question) is incomplete: "**Out-of-Network cost sharing structure for this plan**". It reads: "***If a plan chooses this option and does not utilize either a differential in cost sharing or a differential in days supply for out of network coverage, "** NOTE: This appears on the Deductible and Pre-ICL screens.

- **Formulary**

RxNorm on the PA File will cause separation of policies with like drugs (where they are grouped together as one today). This increases the burden on the validation process.

Also, will there be, and if so what will be the source of a crosswalk of NDCs to RxNorm. We currently do not support RxNorm.

During your review if you have questions or require additional information, please feel free to contact Sally Scott, sscott@humana.com, at 502/580-3161.

Sincerely,

Sally Scott RV

Sally Scott
Regional Director, Regulatory Compliance
Humana Inc.

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MedImpact
Delivering · Flexible · Choice

CMS, Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development – C
Attention: Bonnie L. Harkless
Room C4-26-05
7500 Security Blvd.
Baltimore, MD 21244-1850

December 5, 2008

RE: ***Draft 2010 Plan Benefit Package (PBP) and Formulary Submission Public Comment Period***

Dear Ms. Harkless:

In response to the CMS request for public comment, please find enclosed a list of questions, comments, and suggestions from MedImpact Healthcare Systems, Inc®.

We would appreciate consideration of our recommendations, and would be particularly grateful for answers to our questions. With the introduction of RxNorm information in the 2010 formulary processes, we have undertaken a series of significant projects within our company in order to comply, and CMS responses to our questions is key to our ability to do so efficiently and accurately.

If you have any questions, please do not hesitate to contact me.

Thank you.

Respectfully,

Jim Ayers, RPh.
Director, Formulary Services

TEL: 858.790.7197
Email: Jim.Ayers@MedImpact.com

Questions and Comments from MedImpact Healthcare Systems®

Regarding: ***Draft 2010 Plan Benefit Package (PBP) and Formulary Submission Public Comment Period***

1. What file format and data fields will be provided in the Formulary Reference File (FRF) for 2010? While we understand that the actual file and data will not be available until it is complete, it is critical to us to understand the file specifications from a programming standpoint in preparation for 2010 formulary submissions.

2. Will CMS continue to provide a FRF "Change File"? If so, what file format and data fields will be included?

3. Certain products currently contained on the FRF do not have RxCUI values. How will CMS identify these in the FRF and how will these be expected to be reported in the formulary flat file?
    a. Examples:
        i. Diabetic Supplies
        ii. Prenatal Vitamins
        iii. New drug entities
        iv. Multi-ingredient drug compounds
            1. CHLORIDE ION AND DEXTROSE (ANHYDROUS) AND LACTATE ANION AND MAGNESIUM (+2) AND PHOSPHATE

4. Relative to normalizing Quantity Limits to a basis of 31 days, how should plans represent quantity limits where the amount "per-fill" is limited and there is no limitation based on time? The previous methodology to represent quantity per fill, whereby a day supply value of 1 was utilized in the submission, is no longer possible under the revised file format. Representing quantity per fill as a multiple of 31 would grossly misrepresent the intent of the limitation. We suggest that CMS consider the following:

    Change "Quantity Limit YN" field to "QL Type". This would be analogous to the PA type field in the current ASCII file. Possible values include:

    0 = no QL
    1 = Regular QL (normalized to 31ds)
    2 = Quantity Limit per fill

5. The coverage duration field in the PA file has a length of 100 characters. To clearly describe coverage duration, it would be helpful to provide a larger field length of 300 characters.

6. Please clarify the Formulary File record layout relative to the last three fields: Step_Therapy_Group_Desc, Step_Therapy_Step_Value, and Step_Therapy_Type. In the draft 2010 record layout, the instructions indicate that the first two of these fields should repeat for each associated Step Therapy. However the final field (Step_Therapy_Type) is not included in this repeating set of fields. We believe that it makes sense to repeat the Type field along with the Group Description and Step Value fields to accurately identify the Step Type for each of the Step Therapy Group/Value combinations for that proxy, as well as to provide concrete record length definition.

7. Related to Step Therapies: If a single Step Therapy Group contains two or more proxies within a single Step Value, there may be situations where the Step Type is different for one proxy than for another. For example, the addition of a new drug entity proxy to a step in mid-year may be applied to all members, while the remaining proxies on that step are associated with new starts only. We request confirmation from CMS that the validation and approval process will handle these multi-type steps.

8. Current PA file draft specifications indicate "optional" status on many fields. To reduce the significant interpretation issues which occurred with the 2009 process, we strongly recommend that CMS consider replacing this language with "sometimes required". Precedence for the "sometimes required" status has already been set via the QL fields within the existing formulary file process and would help to prevent misunderstanding of CMS intent for these fields in 2010.

9. Will supplemental formulary files be required in April along with the formulary file submission, or will the deadline for these files continue to occur later in June?

10. For documents and displays where the description of the drug is required (such as in printed Formularies, Member EOB statements, etc), will CMS require the use of the RxNorm "Semantic Normal Name" or will plans be permitted to use existing methods for those descriptions (Brand or Generic Name, Strength, Route, and Dosage Form).