June 28, 2010

Mr. Lou Felice
Chair, Health Care Solvency Impact Subgroup

Dear Mr. Felice:

Thank you for the opportunity to comment on the latest draft of the Blanks form. Using the present structure of the Blanks for QI activities, we have provided some red-line suggestions. In addition to these comments, we continue to believe, as we noted in our last set of comments on June 14, 2010, that the present formulations of QI do not address the full range of quality activities engaged in by payors. We urge you to consider re-working the present draft and use the accepted definitions of quality developed by the Institute of Medicine ("IOM"), the National Priority Partnership ("NPP") and other collaborative organizations (including those supported by Health and Human Services) who have considered how to drive system transformation. Those organizations have affirmed the role of the payor in driving change and in ways not recognized by the present draft. As a matter of framework, we suggest:

- The replacement of the present definiational elements as expressed by the Columns with the six standards developed by IOM (safety; timeliness; efficiency; effectiveness; equitable care and patient-centered care).

- The use of the NPP elements to help flesh out and define the IOM standards through examples of consumer engagement with education; improving population health; coordinating care of patients; patient safety; managing appropriate use and over-use of services and enhancing care and outcomes in life-limiting illnesses.

- The use of some of the present Columns as further examples.

The following are a few examples of important quality efforts not recognized by the present Blanks but which are consistent with IOM and NPP's standards. We have not edited the Blanks to address these topics in as fulsome a way as would be warranted if IOM and NPP standards were employed.

- **Equitable care.** Addressing disparity in care between different populations (such as race, ethnicity, language, gender) is not only a health issue, it is ultimately a pressing social issue. The present Blanks do not address this issue.

- **Efficiency.** Elimination of over-use and waste is included in the IOM's six aims of quality. Preventing hospital readmissions is absolutely essential, but represents but one example of the overall goal of eliminating over-use and waste. In addition to the IOM, the NPP and the NCQA accreditation programs address the need to eliminate over-use, mis-use and under-use of services. Furthermore, effective UM/UR programs are explicitly intended to address improvement in health outcomes and reduce unnecessary costs. Any reduction in hospitalization rates, potentially avoidable hospitalizations, lengths of stay in hospitals and readmission rates are all correlated with increases in quality. Medical research has documented a 6% daily complication rate during hospitalization, regardless of diagnosis or procedure.
• **Fraud and abuse.** If, in fact, efficiency and appropriate use are legitimate aims of quality, which the IOM, the NCQA, and the NPP all contend, then fraud prevention are legitimate services required to improve quality. For example, duplicate or extraneous services and operations represent an adverse impact on the quality of patients, and that can be detected through fraud prevention programs.

• **Network Activities.** In pay for performance and other performance-based contracting programs, quality measures are an essential component of the reimbursement model – and changing the reimbursement model has been recognized as an essential quality effort that can transform the system by eliminating waste. Improving quality and managing costs are an explicit objective of network contracting. Moreover, credentialing is a program wholly dedicated to quality, including review and confirmation of professional training and experience, review of any adverse judgments or determinations made against a provider, and monitoring of any corrective action plans.

• **Measurement.** There are many appropriate programs that may not produce verifiable results. For example, there are many examples of wellness programs and care management programs, such as smoking cessation, weight management, immunization campaigns, diabetes prevention, or other chronic disease management programs, which may not produce desired results, but, nonetheless, are integral to a health care quality improvement program. Additionally, requiring measurement presents the inevitable problems of the period, the metrics at issue, the ability to detect change, the measurement standard and of stifling innovation. If by measurement the concern sought to be addressed is the validity of the program, that issue would seem to be already addressed by QI definition’s requirement that the programs be grounded in the best medical evidence.

We believe that if the driving aim of PPACA is to drive quality care at a lower price the IOM and NPP standards (and the full role of the payor in those efforts) needs to be embraced.

Sincerely,

Thomas J. McGuire
Senior Deputy General Counsel

**ALTERNATIVE APPROACH FOR HANDLING OTHER QI EXPENSES**

Improving Health Care Quality Expenses – General Definition:

Quality Improvement (QI) expenses are expenses, other than those billed or allocated by a provider for care delivery (i.e., clinical or claims costs), for health services that are designed to improve health care quality and increase the likelihood of desired health outcomes in ways that are capable of being objectively measured and which produce verifiable results and achievements. These expenses must be directed toward individual enrollees or may be incurred for the benefit of specified segments of enrollees, recognizing that such activities may provide health improvements to the population beyond those enrolled in coverage as long as no additional costs are incurred due to the non-enrollees. Qualifying QI expenses should be grounded in evidence-based medicine, widely accepted best clinical practice, or criteria issued by recognized professional
medical associations, accreditation bodies, government agencies or other nationally recognized health care quality organizations. They should not be designed primarily to control or contain costs, and the improvement must be capable of being objectively measured and produce verifiable results and achievements. Qualifying QI activities are primarily designed to achieve the following goals set out in Section 2717 of the PHSA and Section 1311 of the PPACA:

- Improve health outcomes including increasing the likelihood of desired outcomes compared to a baseline and reducing health disparities among specified populations;
- Eliminate overuse and waste while ensuring delivery of appropriate care, including preventing hospital readmissions;
- Improve patient safety and reduce medical errors, lower infection and mortality rates;
- Increase wellness and promote health activities; or
- Enhance the use of health care data to improve quality, efficiency, transparency, and outcomes.

NOTE: Expenses which otherwise meet the definitions for QI but which were paid for with grant money or other funding separate from premium revenues shall NOT be included in QI expenses.

PARTS 3A and 3B

COLUMNS:

Column 1 – Improve Health Outcomes

Expenses for the direct interaction of the insurer (including those services delegated by contract for which the insurer retains ultimate responsibility under the insurance policy), providers and the enrollee (e.g., face-to-face, telephonic, web-based interactions or other means of communication) to improve health outcomes as defined above. This category can include costs for associated activities such as:

- Effective case management, Care coordination, and Chronic Disease Management, including:
  - Patient centered intervention such as:
    - Making/verifying appointments,
    - Medication and care compliance initiatives,
    - Arranging and managing transitions from one setting to another (such as hospital discharge to home or to a rehabilitation center), and
    - Reminding insured of physician appointment, lab tests or other appropriate contact with specific providers;
- Incorporating feedback from the insured to effectively monitor compliance;
- Providing coaching to encourage compliance with evidence based medicine;
- Activities to identify and encourage evidence based medicine, including enrollee, physician and hospital engagement programs;
- Use of the medical homes model as defined for purposes of section 3602 of PPACA; and
- Medication and care compliance initiatives, such as checking that the insured is following a medically effective prescribed regimen for dealing with the specific disease/condition and incorporating feedback from the insured in the management program to effectively monitor compliance;
- Centers of Excellence programs;
- Expenses associated with identifying and addressing ethnic, cultural or racial disparities in effectiveness of identified best clinical practices and evidence based medicine;
- Quality reporting and documentation of care;
- Peer review and quality of care reviews;
- Health information technology expenses to support these activities (report in Column 5 - see instructions) including:
  - Data extraction, analysis and transmission in support of the activities described above,
  - Performance measurement to identify and help close any gaps in quality of care and appropriate use of services; and
  - Activities designed to promote sharing of medical records to ensure that all clinical providers have access to consistent and accurate records from all participants in a patient's care; and
- Quality improvement programs to assure appropriate systems, processes, and outcomes are implemented and to ensure continuous compliance, review, measurement and improvement of all clinical management programs.

Column 2 - Activities to eliminate overuse and waste while ensuring delivery of appropriate care, including preventing hospital readmissions

Activities to Prevent Hospital Readmission

Expenses for implementing activities to prevent hospital readmissions as defined above, including:
- Pre-service review and authorization to assess appropriateness of diagnostic or treatment services, based on scientific evidence and subscriber agreements;
- Comprehensive concurrent hospital review to ensure care treatment plans are consistent with clinical guidelines and effectuated expeditiously, as well as to mitigate hospital-acquired conditions;
• Comprehensive discharge planning (e.g., arranging and managing transitions from one setting to another, such as hospital discharge to home or to a rehabilitation center) in order to help assure appropriate care that will, in all likelihood, avoid readmission to the hospital;
• Post discharge reinforcement of care instructions by an appropriate health care professional; and
• Health information technology expenses to support these activities (report in Column 5 – see instructions) including,
  o Data extraction, analysis and transmission in support of the activities described above, and
  o Performance measurement to identify and help close any gaps in quality of care and ensure appropriate use of services; and
  o Activities designed to promote sharing of medical records to ensure that all clinical providers have access to consistent and accurate records from all participants in a patient’s care; and
• Activities to identify and encourage evidence based medicine, including enrollee, physician and hospital engagement programs;
• Assessment of emerging medical technology to ensure that consumers have access to credible and appropriate services;
• Development of medical policies to ensure coverage for appropriate services;
• Payment accuracy programs, including detection and management of fraud and abuse, as well as coordination of benefits, subrogation, claim coding management programs, etc.

Column 3 – Improve Patient Safety and Reduce Medical Errors
Expenses for implementing activities to improve patient safety and reduce medical errors as defined above through:
• The appropriate identification and use of best clinical practices to avoid long term harm;
• Activities to identify and encourage evidence based medicine in addressing independently identified and documented clinical errors or safety concerns;
• Comprehensive discharge planning (e.g., arranging and managing transitions from one setting to another, such as hospital discharge to home or to a rehabilitation center) in order to help assure appropriate care that will, in all likelihood, avoid readmission to the hospital;
• Post discharge reinforcement of care instructions by an appropriate health care professional; and
• Activities to identify and encourage evidence based medicine, including enrollee, physician and hospital engagement programs;
- Activities to lower risk of facility acquired infections;

Column 4 – Wellness & Health Promotion Activities

Expenses for programs that provide wellness and health promotion activity as defined above (e.g., face-to-face, telephonic or web-based interactions or other forms of communication), including:

- Wellness assessment;
- Wellness/lifestyle coaching programs designed to achieve specific and measurable improvements;
- Coaching programs designed to educate individuals on clinically effective methods for dealing with a specific chronic disease or condition; and
- Coaching or education programs and health promotion activities designed to change member behavior (e.g., smoking, obesity); or

Column 5 – HIT Expenses for Health Care Quality Improvements

The PPACA also contemplates “Health Information Technology” as a function that may in whole or in part improve quality of care, or provide the technological infrastructure to enhance current QI or make new QI initiatives possible. Include HIT expenses required to accomplish the activities reported in Columns 1 through 4 that are designed for use by health plans, health care providers, or enrollees for the electronic creation, maintenance, access, or exchange of health information in the following ways:

1. Measuring and monitoring of utilization, cost, and quality data on a real-time basis to ensure appropriate use of services, comportment with evidence-based medicine and clinical guidelines, as well as alignment with benefit designs;
2. Measuring and monitoring of performance assessment of physicians and hospitals and other care providers, in order to assess quality and cost results, including hospital readmissions and potentially preventable conditions, so that continuous improvement can be managed;
3. Development of Electronic Medical Records and Personal Health Records, in order to improve health outcomes and eliminate over-use an inappropriate use of services—e.g., e-prescribing programs to reduce adverse drug events, or drug-drug interactions, or selection of cost-effective choices for patients;
4. Development of HIT programs to comply with “meaningful use criteria” established by the Office of the National Coordinator (ONC) in HIT, including clinical decision support, longitudinal patient registries, and appropriate use criteria;
5. Monitoring, measuring, or reporting clinical effectiveness including reporting and analysis costs related to maintaining accreditation by nationally recognized accrediting organizations such as NCQA or
URAC; or costs for public reporting of quality of care, including costs specifically required to make accurate determinations of defined measures (e.g., CAHPS surveys or chart review of HEDIS measures and costs for public reporting mandated or encouraged by law;

6.2—Advancing the ability of enrollees, providers, insurers or other systems to communicate patient centered clinical or medical information rapidly, accurately and efficiently to determine patient status, avoid harmful drug interactions or direct appropriate care – this may include Personal Health Records accessible by enrollees and appropriate providers to monitor and document an individual patient’s medical history;

7.3—Tracking whether a specific class of medical interventions or a bundle of related services leads to better patient outcomes; or

8.4—Reformatting, transmitting or reporting data to national or international government-based health organizations for the purposes of indentifying or treating specific conditions or controlling the spread of disease.

Exclude: Costs associated with establishing or maintaining a claims adjudication system, including costs directly related to upgrades in HIT that are designed primarily or solely to improve claims payment capabilities or to meet regulatory requirements for processing claims (e.g., costs of implementing new administrative simplification standards and code sets adopted pursuant to the Health Insurance Portability and Accountability Act (HIPAA), 42 U.S.C. 1320d-2, as amended, including the new ICD-10 requirements).

Expense Allocation: A separate, regulator only supplemental filing must be made by the insurer to provide a description of the method utilized to allocate QI expenses to each State and to each line and column on Part 3. Additionally, companies reporting QI expenses in columns 1 through 5 must include a detailed description of such expense elements, including how the specific expenses meet the definitions above. For a new initiative that otherwise meets the definition of QI above but has not yet met the objective, verifiable results requirement, include an “N” in the “New” column of the supplement and include in the description the expected timeframe for the activity to accomplish the objective, verifiable healthcare quality improvement. For the QI portion of each item generally excluded listed below, such as 24 Hour Medical Professional Hotlines and Utilization Review, include a separate description and include an “E” in the “New” column of the supplement. These will be reviewed for adherence to the definition and standards of QI and may be specifically incorporated into, or excluded from, the instructions for QI for future reporting purposes.
Note: 24 Hour Medical Professional Hotlines: Expenses for 24 medical professional nurse hotlines should be included in Improve Health Outcomes, Activities to Prevent Hospital Readmissions, Improve Patient Safety and Reduce Medical Errors, and Wellness & Health Promotion Activities. Any other expenses for 24 hour medical professional hotlines (e.g., answering member questions) should be excluded from Improving Health Care Quality Expenses and instead included in Claims Adjustment Expenses.

Elements of the following items are excluded to the extent they do not meet the General Definition of Quality Improvement expenses set forth above and are designed solely or primarily to control or contain costs. The burden shall be on the proponent to show that the expenses for the programs conform to the definition (and this must be included in the description of the separate, supplemental filing described above). Please See Comment Letter

- 24 Hour Medical Professional Hotlines (except as noted above);
- Utilization Review (all retrospective and concurrent review is excluded from QI); Comments will be taken on concurrent U/R activities
- Fraud Prevention activities (all activities related to recoupment of fraudulent payments are excluded – only expenses that can be directly tied to Column 3, Improve Patient Safety and Reduce Medical Errors, expenses may be included in QI);
- Network Management (all fees and expenses related to establishing or maintaining the network are excluded from QI);
- Provider Contracting and Credentialing (the cost of developing and executing provider contracts would be excluded);
- Accreditation Fees (under Subgroup review);
- Costs associated with calculating and administering individual enrollee or employee incentives. (rewards or bonuses associated with wellness or health promotion programs are excluded) The e.g., reductions in individual enrollee or group health plan copays, deductibles or premiums based on achieving specified health outcomes or engaging in specified health promotion activities) (if clarifications need to be made, suggest language);
- Any function not expressly included in Columns 1 through 5.