



PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION

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Mr. Steve Ostlund  
Chair, Accident & Health Working Group  
c/o National Association of Insurance Commissioners  
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Mr. Lou Felice  
Chair, Health Care Reform Solvency Impact Subgroup  
c/o National Association of Insurance Commissioners  
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Dear Mr. Ostlund and Mr. Felice:

On behalf of the Pharmaceutical Care Management Association (PCMA), we appreciate this opportunity to offer our comments as the Accident & Health Working Group and the Health Care Reform Solvency Impact Subgroup consider uniform definitions and standardized methodologies for calculating the “medical loss ratios” (MLR) provisions of § 2718 – “Bringing Down the Cost of Health Care Coverage” – of the Public Health Service Act added by the Patient Protection and Affordable Care Act (PPACA).

PCMA is the national association representing America’s pharmacy benefit managers (PBMs), which administer prescription drug plans for more than 210 million Americans with health coverage provided through Fortune 500 employers, health insurers, labor unions, Medicare, Medicaid, and the Federal Employees Health Benefits Program.

PCMA believes that the definition of quality improvement that the Working Group is developing is too narrow in scope. The Working Group’s definition only applies to programs where there is a direct relationship between quality and the care provided to a particular individual. PCMA believes that this definition excludes many important programs that improve quality. The definitions of quality improvement included in Section 5 of the Supplemental Health Care Exhibit should allow for the inclusion of a broad array of functions and activities that provide for improved patient care, safety, and combating fraud and abuse. These functions should be encouraged as they serve the goals – outlined in health care reform – of improving health care quality, containing cost, and preventing waste while providing broad health care coverage.

The current draft excludes all utilization review activities from the definition of quality improvement. However, the utilization review process as it is conducted between a PBM and a pharmacy involves a myriad of functions that improve quality. For example, drug utilization review (DUR) includes a real-time check of all medications that a patient has filled and notifies the pharmacist through electronic alerts as to whether there is a contraindication of a potential adverse event. In addition, the U.S. Food and Drug Administration (FDA) requires labeling information about whether a drug requires physician diagnosis or other information before being filled. This

information is conveyed through a prior authorization process included in the DUR system. Considering the increasing complexity and potential toxicity of drug therapies, it is more important than ever to avoid dispensing inappropriate therapies.

The development and management of a formulary is another example of a quality improvement program that might fall outside the Working Group's present definition of a quality improvement program. Formularies are a key component to providing access to safe and effective medications at the lowest possible price. Through independent pharmacy and therapeutics (P&T) committees, formularies are continually updated and maintained. P&T committees comprise of physicians, specialists, pharmacists, and others, and consider data about the drug development during the clinical trial period, FDA information about the safety profile, and economic information. P&T committees continually review drugs post-approval, as additional information is learned about their safety or effectiveness.

Other pharmacy management functions that improve quality are clinical activities typically undertaken by pharmacies, such as chronic disease management, 24-hour pharmacist hotlines, preventive care and wellness programs, and care coordination. Specialty pharmacies also utilize clinical programs to ensure that patients receive special instruction on how to take these medications properly. Another important pharmacy management function is e-prescribing. The demonstrated benefits of e-prescribing include reducing adverse drug events and increasing efficiency of the health care system. All of these functions play an important role in improving quality of care. Unfortunately, many of these programs might not fall under the Working Group's narrow interpretation of quality improvement. It should be the goal of public policymakers to encourage these programs. An important tool in encouraging these programs will be to include them in quality improvement component of PPACA's medical loss ratio formula.

PCMA is also concerned that the Working Group's limited definition of quality improvement is contrary to the legislative intent found elsewhere in PPACA and that it does not include quality improvement programs that have been mandated by law. PPACA, taken as a whole, does not support the notion that "activities to improve quality" only apply to activities improving quality for a particular patient. PPACA's minimum loss ratio provision does not define what constitutes "activities that improve health care quality." Absent a specific definition, PCMA believes that the NAIC should turn to other provisions of the statute for guidance as to the types of activities that Congress believes improve health care quality. For example, Section 2717 of PPACA, which is entitled "Ensuring the Quality of Care," includes many examples of activities Congress evidently believes improves the quality of care. These include "quality reporting, effective case management, care coordination, chronic disease management, and medication and care compliance initiatives." Also included are "activities to improve patient safety and reduce medical errors through the appropriate use of best clinical practices, evidence based medicine, and health information technology under the plan or coverage." Finally, Congress also included wellness and health promotion activities in the list of activities that should be promoted because they improve the quality of care. Unfortunately, it appears that many of these activities are excluded under the Working Group's present definition.

Also excluded are some of the programs that are mandated under state and other federal laws. Activities mandated under state, local, and federal laws that require insurers, and/or their subcontractors, to engage in activities to improve quality should be included within the NAIC final definition of activities that improve health care quality. If there is a state, local, or federal

determination that a function or activity is intended to improve quality, the NAIC should honor that determination.

PCMA also believes that the Working Group's proposed loss ratio formula does not include all of the elements contained in PPACA or in the formula articulated by U.S. Department of Health and Human Services (HHS). PPACA includes loss-adjustment expense in its definition of the loss side of the medical loss ratio. In addition to change in contract reserves, the loss adjustment expense should include provisions for expenses for fraud detection and prevention. HHS, in its request for comments published in the Federal Register, also acknowledges that loss adjustment expenses are part of the loss ratio formula. In the Federal Register, HHS stated medical loss ratio (MLR) as the ratio of the incurred loss (or incurred claims) plus the loss adjustment expense (or change in contract reserves) to earned premiums. *See Fed. Reg. Vol. 75, No. 71, page 19299.* Therefore, the loss adjustment expenses associated with fraud detection and prevention activities should be included in the loss ratio formula.

With regard to fraud prevention, pharmacy management programs provide data to state-controlled substance tracking systems, to monitor individuals' prescription fills and help prevent individuals from doctor and pharmacy shopping to obtain illegal quantities of pain killers or other controlled substances. This key function not only advises law enforcement, but provides critical information to pharmacists and physicians to avoid inappropriate prescribing and dispensing. Congress clearly wants private insurers to continue fraud detection efforts. Indeed, to help facilitate further investigation of suspected fraud and abuse, PPACA directs the Secretary of HHS to request the NAIC to develop a model uniform report form for private insurers seeking to refer suspected fraud and abuse situations to individual state insurance departments and other state agencies for investigation.

Finally, it is imperative that any definition or listing of activities that improve health care quality should be flexible and should outline the *types* of "activities to improve health care quality" to be included, but should not be intended as an exhaustive list. It is impossible to take into account every program that would improve patient safety, reduce medical errors, or increase adherence to treatment. It is also impossible to predict important quality improvement activities that might be developed in the future.

We appreciate the opportunity to comment as you consider these important issues.

Sincerely,



Barbara A. Levy  
Vice President and General Counsel  
Pharmaceutical Care Management Association

cc: John Engelhart, NAIC Staff  
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