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Request for Comments Regarding Section 2718 of the Public Health Services Act (Medical Loss Ratios)

The Academy of Managed Care Pharmacy (AMCP) is pleased to provide comments to the National Association of Insurance Commissioners (NAIC) on implementation of Section 2718 of the Public Health Services Act relating to medical loss ratios.

AMCP is a national professional association of pharmacists and other health care practitioners who serve society by the application of sound medication management principles and strategies to achieve positive patient outcomes. The Academy's 6,000 members develop and provide a diversified range of clinical, educational and business management services and strategies on behalf of the more than 200 million Americans covered by a managed care pharmacy benefit. They are responsible for a broad and diversified range of clinical, quality-oriented services, programs and strategies including the development and implementation of drug formulary systems.

The provisions of Section 2718 of the Public Health Service Act (PHS Act), which were added by Sections 1001 and 10101 of the Patient Protection and Affordable Care Act (PPACA), P.L. 111-148, require health insurance issuers to submit data on the proportion of premium revenues spent on clinical services and activities that improve health care quality, also known as the medical loss ratio (MLR), and to provide rebates to enrollees if this spending does not meet minimum standards for a given plan year.

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The PPACA sets an 85 percent minimum standard in the large group market for the percentage of premiums that coverage spends on reimbursement for clinical services and activities that improve quality. It sets an 80 percent minimum standard for the small group and individual markets.

Section 2718(a) of the PHS Act requires health insurance issuers offering group or individual coverage to submit a report to the Secretary for each plan year, concerning the ratio of the incurred loss (or incurred claims) plus the loss adjustment expense (or change in contract reserves) to earned premiums. Section 2718(c) directs the NAIC to establish uniform definitions of the activities being reported to the Secretary and standardized methodologies for calculating measures of these activities no later than December 31, 2010. These uniform definitions and standardized methodologies that NAIC develops are to be subject to the certification of the Secretary. It is noteworthy that the Secretary, pursuant to Section 2718(d), may adjust the rates if determined appropriate based on the volatility of the individual market due to the establishment of State Exchanges.

The fundamental question before the NAIC is what qualifies as a medical cost for purposes of calculating MLR. AMCP submits that the definition of MLR should recognize essential legislative priorities designed to enhance patient care including medication therapy management (MTM) programs, health information technology (HIT), formulary development, coordinated care activities, and fraud prevention activities.

In the commercial health insurance industry, “medical loss ratio,” or MLR, is defined as the percentage of each premium dollar that insurers spend on providing health care to their customers.¹ For example, if 80 cents of each premium dollar are used to pay medical claims for a health plan’s members, the company has an MLR of 80 percent. An MLR of 80 percent indicates that the insurer is using the remaining 20 cents of each premium dollar to pay expenses that do not directly benefit policyholders, such as salaries, agent commissions, advertising, overhead and profits.

Section 2718(a) of the PHS Act defines MLR as “the percentage of the total premium revenue ... that such coverage expends –

- (1) On reimbursement for clinical services provided ...;
- (2) For activities that improve health care quality; and
- (3) On all other non-claims costs, including an explanation of the nature of such costs, and excluding Federal and State taxes and licensing or regulatory fees.”

MLR calculations clearly include dollars paid by an insurer to reimburse health care providers for medical services covered under an insured’s policy. AMCP believes the costs incurred by health plans providing both clinical and non-clinical services that either directly or indirectly improve the health care quality delivered to health plan members are legitimately covered under MLR. These services include:

- MTM programs
- Formulary management, including formulary development, formulary exception processes and prior authorization programs
- Coordinated care activities
- Health care quality improvement activities
- Disease management programs
- Health coaching activities
- Transitional care activities
- Quality measurement activities

¹ Office of Oversight and Investigations Majority Staff, Senate Committee on Commerce, Science and Transportation, *Implementing Health Insurance Reform: New Medical Loss Ratio Information for Policymakers and Consumers*, April 15, 2010. <http://www.pnhp.org/sites/default/files/docs/2010/MLR-Report.pdf> (accessed May 6, 2010)

- Health information technology (HIT) development
- Fraud prevention activities

Medication Therapy Management (MTM) Programs

MTM programs are offered by health plans and other organizations to optimize therapeutic outcomes by improving the use of medications by patients with chronic conditions and multiple medications and to avoid adverse drug events and unnecessary costs.

MTM programs are designed to improve collaboration among pharmacists, physicians, and other health care professionals; enhance communication between patients and their health care team; and optimize medication use for improved patient outcomes. MTM services empower patients to take an active role in managing their medications. The services are dependent upon pharmacists working collaboratively with physicians and other healthcare professionals to optimize medication use in accordance with evidence-based guidelines. MTM services are distinct from medication dispensing and focus on a patient-centered, rather than an individual product-centered, process of care. These services encompass the assessment and evaluation of the patient's complete medication therapy regimen, rather than focusing on an individual medication product. MTM services help address the urgent public health need for the prevention of medication-related morbidity and mortality. MTM services contribute to medication error prevention, result in improved reliability of healthcare delivery, and enable patients to take an active role in medication and healthcare self-management.² Confidence in the value MTM programs provide to particularly high risk patients is evidenced by their inclusion as a required offering by all Medicare Part D plan sponsors and by provisions in the PPACA.

Health plans may contract with pharmacists or other health care practitioners to provide MTM services; in this case such services would be billed to the health plan and be considered as "reimbursement for clinical services provided," falling under Section 2718(a)(1). Health plans may also provide MTM services through pharmacists or other health care practitioners employed by the health plan. AMCP believes NAIC should classify all MTM services as activities that improve health care quality, falling under either Section 2718(a)(1) or (2).

Formulary Management

AMCP believes formulary management is an area that NAIC should classify as part of the MLR calculation under Section 2718(a)(2). Formulary management is an integrated patient care process which enables physicians, pharmacists and other health care professionals to work together to promote clinically sound, cost-effective medication therapy and positive therapeutic outcomes. Effective use of health care resources can improve patient access to more affordable care, provide an improved quality of life, and minimize overall medical costs.

A drug formulary, or preferred drug list, is a continually updated list of medications and related products supported by current evidence-based medicine, judgment of physicians, pharmacists and other experts in the diagnosis and treatment of disease and preservation of health. The primary purpose of the formulary is to encourage the use of safe, effective and most affordable medications.

A formulary system includes the methodology an organization uses to evaluate clinical and medical literature and the approach for selecting medications for different diseases, conditions and patients. Policies and procedures for the procuring, dispensing, administering and appropriate utilization of medications are also included in the system. Formulary systems often contain additional prescribing guidelines and clinical information which assist health care professionals to promote high quality, affordable care for patients. Finally, for quality assurance purposes, managed health care systems that use formularies have policies in place to give physicians and patients access to non-

² American Pharmacists Association and National Association of Chain Drug Stores Foundation, *Medication Management in Pharmacy Practice: Core Elements of an MTM Service Model*, Version 2.0., 2008.

formulary drugs where medically necessary through formulary exception processes. Prior authorization can be used for drugs that have a high potential for misuse or inappropriate use. Health plans may limit coverage of drugs to FDA-approved uses, or for unapproved, or off-label, uses that are supported by adequate medical evidence.

The medications and related products listed on a formulary are determined by a pharmacy and therapeutics (P&T) committee or an equivalent entity. P&T committees are comprised of primary care and specialty physicians, pharmacists and other professionals in the health care field. Often P&T committees also include nurses, legal experts, and administrators. The P&T committee is responsible for developing, managing, updating and administering the formulary. Utilization management strategies such as quantity limits, step therapy and prior authorization criteria may be reviewed and approved by P&T committees. Access policies include medical exception process protocols to allow patients coverage for non-formulary drugs under defined circumstances.³

P&T committees evaluate medications after Food and Drug Administration (FDA) approval. Due to the multiplicity of medications on the market and the continuous introduction of new medications, a formulary must be a dynamic and continually revised listing. In order to keep a formulary current, the P&T committee meets regularly to review newly released drugs and/or classes of drugs. The P&T committee reviews some or all of the following:

- Medical and clinical literature including clinical trials and treatment guidelines, comparative effectiveness reports, pharmacoeconomic studies and outcomes data;
- FDA-approved prescribing information and related FDA information including safety data;
- Relevant information on use of medications by patients and experience with specific medications;
- Current therapeutic use and access guidelines and the need for revised or new guidelines;
- Economic data, such as total health care costs, including drug costs;
- Drug and other health care cost data; and
- Health care provider recommendations.

Formulary systems evolve as new information becomes available or resources are developed. Since formulary decisions rely on published clinical information to make those decisions, it is important to have as much quality information as is available. It is estimated that in the coming years, comparative effectiveness research (CER) and genetic-based medicine, also referred to as personalized medicine, will impact formulary systems. The information gained through CER methodology and outcomes will provide P&T committees additional resources to evaluate the use of medication versus alternative treatment options. Through diagnostic tests and targeted therapies, personalized medicine may add complexity to the P&T committee decision making process. P&T committees will have to develop policies and procedures for making individual decisions in addition to the traditional population-based decisions.⁴

A quality formulary management system contributing to the use of the safest and most effective medications requires considerable management by the health plan at a significant cost. Formulary management clearly fits the definition of an activity that improves health care quality and should therefore be classified by NAIC as part of the MLR calculations under Section 2718(a)(2).

Additional Clinical Services

Additional services that should be considered activities that improve health care quality and be considered part of the MLR calculations under Section 2718(a)(2) are:

³ Academy of Managed Care Pharmacy. *Concepts in Managed Care Pharmacy Series – Prior Authorization and the Formulary Exception Process*. 2005. <http://www.amcp.org/amcp.ark?p=AAAC630C> (accessed May 6, 2010)

⁴ Academy of Managed Care Pharmacy, *Concepts in Managed Care Pharmacy Series – Formulary Management*. 2010. <http://www.amcp.org/amcp.ark?p=AAAC630C> (accessed May 6, 2010)

- Coordinated care activities
- Prior authorization programs
- Health care quality improvement activities
- Disease management programs
- Health coaching activities
- Transitional care activities

It has been well documented that initiatives focused on encouraging patient self-management of chronic diseases translate into improved health care quality. One example of success from such a program is the Asheville Project conducted by pharmacists in Asheville, North Carolina. Two employers, the City of Asheville and Mission-St. Joseph's Health System, participated in two initiatives targeting [asthma](#) and diabetes. A total of 194 employees met the criteria for participation in the diabetes program. The study assessed both clinical and economic outcomes for up to five years. For patient enrolled in the program, mean hemoglobin A1c levels, a measure of diabetes control, decreased (improved) at every follow-up. Mean HDL-C levels, a measure of cholesterol control, increased (improved) at every follow-up.⁵

For health plans to continue to fund such programs at the level necessary to see improvements in health care quality, these clinical services must be classified as part of the MLR calculations under Section 2718(a)(2).

Quality Measurement Activities

Increasingly, health plans are expected to participate in quality improvement programs and to report the results not only to improve their internal operations but also to report to third-party payors, government agencies, organizations that are studying quality, and to the public. Health plans must have adequate and appropriate structures and processes in place to monitor and evaluate the quality and effectiveness of health care delivery. Many quality improvement initiatives require additional resources such as staff time, communication development and dissemination, and measurement.

A health plan can seek to assess quality using objective standards and measures. Meeting selected performance standards and measures requires an organization to provide evidence typically in the form of documentation and/or data reports. The following are examples of existing measures from which health plans select:

- Compliance with standards or measures required for voluntary, third-party accreditation
- Performance measures required by a government agency
- Evidence of compliance with voluntary accreditation or government-mandated standards or measures for existing or prospective client(s)
- Internal quality improvement initiatives or projects.

For commercial health plans, the National Committee for Quality Assurance's (NCQA's) Healthcare Effectiveness Data and Information Set (HEDIS®) measures serve as a recognized standard for measuring quality. The HEDIS measure set is a tool used by more than 90 percent of America's health plans to measure performance on important dimensions of care and service. Each year, NCQA releases its latest edition of Quality Compass, the nation's leading database of comparable information on clinical performance and patient experience. In 2009, this included 415 commercial health plan products serving 94 million enrollees.⁶ It is programs such as those listed above, including disease management programs and health care quality improvement activities, which translate into the health care

⁵ Cranor CW, Bunting BA, Christensen DB. The Asheville project: long-term clinical and economic outcomes of a community pharmacy diabetes care program. *J Am Pharm Assoc.* 2003;43(2):173-184.

⁶ NCQA, NCQA's Quality Compass 2009 Details Performance Data for 415 Commercial Health Plan Products Serving 94 Million Enrollees. <http://www.ncqa.org/tabid/1053/Default.aspx> (accessed May 4, 2010).

quality improvements measured by the HEDIS measure set and reported annually through NCQA's Quality Compass database.

AMCP believes the annual content of NCQA's Quality Compass illustrates the broad use of quality measurement as a standard element in health plan delivery of care to its patient populations. As such, AMCP believes both the costs of measuring quality and reporting those measurements must be classified as part of the MLR calculation.

Health Information Technology

Critical to effective patient care is not only the pharmacy arena but across the whole spectrum of responsible patient care are health information technology (HIT) initiatives. AMCP believes HIT initiatives should be classified as part of the MLR calculations under Section 2718(a)(2). Electronic health records and electronic prescribing provide a means to improve access, safety, quality and cost-effectiveness of medication use which is clearly a cornerstone to successful treatment of both acute and chronic health conditions and the ultimate health of a health plan's members.

Effective electronic prescribing and electronic medical records are essential components of medication reconciliation. Medication reconciliation is the comprehensive evaluation of a patient's medication regimen anytime there is a change in therapy in an effort to avoid medication errors such as omissions, duplications, dosing errors, or drug interactions as well as to observe compliance and adherence patterns. This process should include a comparison of the existing and previous medication regimens and should occur at every transition of care in which new medications are ordered, existing orders are rewritten or adjusted, or if the patient has added non-prescription medications to their self-care.

Given the federal commitment to establishing functional national HIT standards designed to improve patient care, it is essential that HIT expenses incurred by health plans be included in the MLR calculations under subsection (2) of Section 2718(a).

Fraud Prevention Requirements

With regard to fraud prevention activities, the PPACA includes significant fraud prevention and program integrity initiatives. Health insurers are required to have in place effective procedures to control fraud, abuse and waste and meet such other requirements as the Secretary may impose. Among the procedures that plans will have to include are the following:

- Implementation of procedures to use beneficiary identifiers to identify individuals entitled to benefits so that such an individual's social security account number is not used, and
- Procedures for the use of technology (including front-end, prepayment intelligent data-matching technology similar to that used by hedge funds, investment funds, and banks) to provide real-time data analysis of claims for payment under this title to identify and investigate billing or order practices that could indicate fraud or abuse.

In addition, the HHS Inspector General will conduct periodic audits with respect to the contracting administrators to determine whether they are in compliance with the requirements. Finally, there are special rules relating to Medicare Parts C and D that require the Secretary to enter into contracts to do, among other things, the following:

- Ensure that each Medicare Advantage plan under Part C has an anti-fraud plan in effect and to review the effectiveness of each such anti-fraud plan; and
- Ensure that each prescription drug plan under Part D has an anti-fraud plan in effect and to review the effectiveness of each such anti-fraud plan.

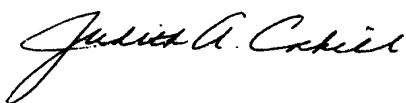
AMCP believes that the fraud prevention activities should be included in the MLR. Including fraud prevention activities as an administrative cost would have the probable outcome of running counter to the interest of investment

by health insurers in fraud, waste and abuse expenses beyond just the minimum necessary to be compliant with the new PPACA requirements. Including fraud, waste and abuse expenses in the MLR calculation, rather than treating them as administrative costs, would encourage health plans to field more robust fraud detection programs and avoid efforts to pare back those activities. Also, efforts to reduce fraud will have the benefit of further supporting and enhancing clinical services that are covered by the MLR.

The PPACA gives significant priority to efforts to reduce fraud, waste and abuse in health care. The Academy urges NAIC to take this fact into consideration when defining and calculating claims costs and non-claims costs.

AMCP appreciates the opportunity to comment on these extremely important issues. If you have any questions, please contact me at (703) 683-8416 or at jcahill@amcp.org.

Sincerely,

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

Judith A. Cahill
Executive Director