

April 29, 2016

The Honorable Tony Lourey Chairman Senate Health and Human Services Budget (HHS) Division Senate HHS Budget Division Minnesota Senate 95 University Avenue W. Room 2105 St. Paul, MN 55155

The Honorable Julie A. Rosen Ranking Minority Member Minnesota Senate 95 University Avenue W. Room 2105 St. Paul, MN 55155

RE: Article 25 – Health Care in SF. No. 2356 – Senate Omnibus Supplemental Appropriations Bill

Dear Senator Lourey, Senator Rosen, and Members of the Senate HHS Budget Division:

The Academy of Managed Care Pharmacy (AMCP) is opposed to the prior authorization language under Article 25 – Health Care in Senate File No. 2356, the Senate Omnibus Supplemental Appropriations Bill because it restricts a health benefit plan's ability to manage its formulary, and it establishes unreasonable standards for the use of prior authorization by health benefit plans. Instead, it replaces these managed care tools with a government mandated design.

AMCP is a national professional association of pharmacists and other health care practitioners, including 295 members in Minnesota, who serve society by the application of sound medication management principles and strategies to improve health care for all. The Academy's nearly 7,000 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.

Article 25 in Senate File No. 2356 would replace the decision making process by physicians and pharmacists with a government restrictive plan that mandates the same process for all health plans with no consideration for the individual patient's needs or the health plan's proven evidence-based approach.

AMCP supports the use of evidence-based formularies that enhance the quality of pharmaceutical care while lowering medication costs. A drug formulary is a continually updated list of prescription medications that represent the current clinical judgment of providers who are experts in the diagnosis and treatment of disease. Formularies often contain additional prescribing and clinical information that assists health care professionals as they promote high quality, affordable care to patients.

AMCP supports a well-designed, evidence-based formulary to assist in effectively managing a patient's total medical care regimen. A formulary enhances the quality of care by encouraging the use of those prescription medications that are demonstrated to be the safest, the most effective, and that produce positive patient outcomes.

A drug formulary may be used in many ways for the administration of a prescription benefit. Formularies may be used to recommend the most appropriate drug choice and assist in the determination of member cost-share or drug coverage. The way a formulary will be utilized is based on many factors, including patient population and benefit design.

A formulary works best when it supports and operates in conjunction with other tools that promote quality and optimal results, such as drug utilization review and medical treatment guidelines. In addition, the value of a formulary is maximized when it is part of an integrated patient care process that encourages physicians, pharmacists, and other caregivers to work together to ensure positive and cost-effective results.

Generally, a formulary is developed and maintained by a Pharmacy & Therapeutics Committee or equivalent entity that meets regularly to review and evaluate the medical and clinical evidence from the literature, relevant patient utilization and experience, economic data, and provider recommendations to determine which drugs are the safest, most effective, and produce the best medical results. The membership of a P&T Committee includes physicians, pharmacists, and other health care professionals who collectively utilize their current knowledge and expertise in clinical aspects of prescription drugs and drug use, depend on evidence-based decision making, evaluation, and intervention. Since a formulary is a dynamic and continually revised document, the P&T Committee regularly evaluates the formulary and adjusts it to reflect the best medical practices and new clinical and economic evidence that may have an impact on which drugs are included or excluded.

Studies show that choice of the most appropriate drug results in fewer treatment failures, reduced hospitalizations, better patient adherence to the treatment plan, fewer adverse side effects, and better overall outcomes. Such efficient and effective use of health care resources helps to keep overall medical costs down, improves the consumer's access to more affordable care, and provides the patient with an improved quality of life.

The primary criteria for the formulary decision-making process should be centered on a drug's safety, efficacy, and effectiveness. A drug's clinical profile, rather than its costs, should be the primary factor in determining whether a drug is included or excluded from the formulary. Members of the P&T Committee use evidence-based decision-making tools and models that relate key factors and probabilities to one another in order to determine the best drugs to have on the formulary. Inputs into this process include clinical trials, scientific studies, an evaluation of the drug's role in disease treatment guidelines, comparisons with other like products, and data that reflect the drug's actual or projected utilization in specific patient populations. In addition, the formulary review process has evolved from one requiring typical efficacy and safety data to one requiring data on health outcomes and actual effects and costs of a drug once it has been commercially released to the general population.

AMCP agrees that for quality assurance purposes, health plans that use formularies should have policies in place to provide for a medical exceptions process. The medical exceptions process allows individuals to request:

- coverage of a prescription drug that is not covered based on the formulary, and
- continued coverage of a drug that has been removed from the formulary for reasons other than safety or because the drug cannot be supplied or has been withdrawn from the market.

Such exceptions should be based only on documented medical need. Health plans currently provide an exceptions process. Therefore, AMCP cannot support the restrictive medical exceptions process mandated in Article 25 in Senate File No. 2356.

Lastly, Article 25 in Senate File No. 2356 expands the definition of "prior authorization" to include "pharmaceutical utilization management procedures," thereby increasing the number of and types of procedures covered as prior authorization. Although the language decreases the time periods for all prior utilization decisions that were contained in the legislation as introduced (standard and expedited review determinations and standard and expedited appeals), it still increases the number and type of procedures subject to the determinations and appeals, but decreases the amount of time that a health plan has to respond. Further, if the utilization review organization does not meet the timelines, then the service is deemed approved. Therefore, AMCP cannot support the decreased time frames, nor the provision that allows services to unilaterally be deemed approved.

AMCP understands prior authorization, utilization review procedures, and formulary placement can be contentious; however, all of these managed care tools utilized by pharmacists are beneficial. Implementation of a well-designed, evidence-based prior authorization program optimizes patient outcomes by ensuring patients receive the most appropriate medications while reducing waste, error and unnecessary prescription drug use and cost. Prior authorization procedures and requirements for coverage are based on clinical need and therapeutic rationale. Administration of a prior authorization process must consider the desired outcome for the patient, the design of the drug benefit, and the value to the plan sponsor.

AMCP appreciates the opportunity to share our views and respectfully urge you to vote against passage of the prior authorization language in Article 25 of Senate File No. 2356. If you have any questions, you may contact AMCP's Director of Legislative Affairs, Reginia Benjamin, at (703) 683-8416 or rbenjamin@amcp.org.

Sincerely,

Susan Cantrell, RPh, CAE Chief Executive Officer

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cc: Members of the Senate Health and Human Services Budget Division