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TO: The Honorable Thomas Mac Middleton, Chair
Members, Senate Finance Committee

FROM: Joseph A. Schwartz, III
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DATE: February 19, 2014

RE: **SUPPORT** – Senate Bill 622 – *Health Insurance – Step Therapy or Fail-First Protocol*

The Maryland State Medical Society (MedChi), which represents more than 8,000 Maryland physicians and their patients, supports Senate Bill 622.

Senate Bill 622 is a culmination of a two-year effort to place reasonable patient protections on the practice known as "step therapy or fail first protocol." Step therapy or fail first protocols are imposed by insurers and, more often, pharmacy benefit managers (PBMs) as a cost saving mechanism. Under these protocols, insurers and PBMS require patients, prior to using the drug preferred by their physician or health care practitioner, to use an alternative drug or drugs first and then be "stepped" to the preferred drug. While insurers and PBMS may argue that step therapy protocols provide appropriate and affordable drug treatments, step therapy can have the opposite effect by unnecessarily prolonging ineffective treatment and preventing patients from immediately starting treatments based on the recommendation of their physician or health care practitioner.

During the 2013 Session, MedChi supported legislation to regulate this practice. While the legislation was unsuccessful, the presiding officers and the Chairs of the Senate Finance and the House Health and Government Operations Committees requested the Maryland Health Care Commission (MHCC) to examine the issue. The MHCC engaged the Mercer Consulting Group to study the practice of step therapy around the country and Mercer produced a comprehensive report. At the same time, the MHCC convened meetings of the stakeholders in an attempt to find common ground and gather information on the practice of step therapy. Unfortunately, two of the major PBMs in Maryland declined to provide information to the MHCC, making data gathering difficult.

The Mercer report made several notable findings, which all center around the common denominator that step therapy protocols vary greatly between insurers and PBMs. Specifically, the Mercer report noted variations among entities in the number of drugs subject to step therapy, the number of steps a patient is required to try, and how step is applied when a patient changes payers. The Mercer report listed five areas for consideration and concluded that these were the areas where "the constituents have common ground that could be forged to put forth a second iteration of the legislation."

The MHCC Report reviewed the analysis provided by the Mercer Group and completed an independent review by examining medications subject to step therapy. In conducting their review, the MHCC also acknowledged that it was difficult, given that the two leading PBMs (estimated to comprise 55% of scripts for privately insured), refused to provide data to the MHCC. In the end, the MHCC made three recommendations which included: 1) standardizing step therapy grandfathering exemptions (a 365 day look back) to permit most patients already managed by a drug to continue with that treatment without having to restart protocols; 2) requiring payers to expand web-based preauthorization systems to accommodate step therapy transactions, such as approvals and waiver requests, by July 2015; and 3) require all payers, including PBMs to submit claim information to MHCC.

Therefore, based on the analysis provided by the Mercer Group and the recommendations put forth by the MHCC, Senate Bill 622 contains four provisions:

- **Grandfathering Exemption**: Permits patients already managed by a drug prescribed within 365 days to continue with that treatment without having to restart step therapy protocols. This change will provide consistency among insurers or PBMs and will benefit patients that change health plans.
- **Override Processes**: Requires payers to incorporate step therapy approval and override processes in their automated preauthorization applications by January 1, 2015. The MHCC report noted that some preauthorization systems may already be able to accommodate step therapy requirements without substantial modification. By requiring a January 1, 2015 implementation date, all required components in the automated preauthorization application will be implemented prior to the July 1, 2015 mandated use by providers.
- **Non-Approved FDA Drugs**: Prohibits payers from requiring physicians and health care practitioners to utilize prescriptions as a component of a "step-therapy" protocol that are not approved by the FDA for the intended use.
- **Duration**: Limits the use of a step therapy protocol to 30 days or any period agreed to by the insured's or enrollee's prescriber and the entity to determine the clinical effectiveness of the step therapy drug. (Included in the Mercer Analysis).

MedChi believes that Senate Bill 622 is extremely important legislation that strikes the correct balance between those who would outlaw step therapy and those who believe that step therapy has a place in controlling the cost of medicines. MedChi would urge a favorable report on Senate Bill 622.

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