



July 30, 2015

Jenifer Bosco, Director
Office of Patient Protection
Health Policy Commission
50 Milk Street, 8th Floor
Boston, MA 02109

Re: Proposed changes to 958 CMR 3.101 – Carrier's Medical Necessity Guidelines
958 CMR 4.00 – Open Enrollment Waivers

Dear Director Bosco:

On behalf of the Massachusetts Association of Health Plans, which represents 17 member health plans that provide health care coverage to approximately 2.6 million Massachusetts residents, I am writing with regard to the Office of Patient Protection's (OPP) proposed changes to 958 CMR 3.101, dealing with Carrier's Medical Necessity Guidelines, and 958 CMR 4.00, concerning Open Enrollment Waivers.

We appreciate the complexities involved in developing these regulations and believe that the proposed changes take a balanced approach. With regard to 958 CMR 3.101, the amendments reflect the relevant state statutory changes included in Chapter 224 of the Acts of 2012 and Chapter 165 of the Acts of 2015 that health plans make utilization review and medical necessity criteria and protocols available to OPP and health plan members, publish this information on their websites, and includes relevant protections for licensed, proprietary criteria that health plans purchase. The proposed changes to 958 CMR 4.00 reflect relevant changes to federal requirements related waivers for individuals to obtain coverage outside of the open enrollment period.

We are concerned that some of the suggestions offered during the public hearing, may increase the cost and complexity of implementing the final regulations and would be inconsistent with current efforts by the Administration to reform and streamline regulatory requirements in the Commonwealth. For example, the suggestion to reduce the time period for plans to respond to requests for medical necessity criteria is unnecessary as there are already statutory requirements in place for shorter timeframes in response to external appeals. Likewise, the suggestion to require health plans to establish a specific telephone line for requests for medical necessity criteria is unnecessary as there is no evidence that health plans are not making this information available. Finally, the suggested changes offered during the July 8 hearing should be analyzed in the context of Executive Order 562 and the Administration's efforts to review whether any costs associated with the regulation exceed the benefits that result from the particular regulation or

whether the regulation exceeds federal requirements or duplicate local requirements. As the changes that OPP has proposed incorporate applicable state and federal statutory and regulatory changes, we would urge that no further revisions be made to the final regulations.

One area that we would suggest for OPP and the Health Policy Commission (HPC) to monitor is the impact the introduction of new, high-cost specialty drugs may have on the requirements related to 958 CMR 3.101. As we have previously outlined in comments to the Commission concerning the 2015 Health Care Cost Trends Hearings, while breakthrough medications offer tremendous clinical benefits for patients, the cost of specialty drugs has risen significantly and broad demand for these expensive drugs has led to significant increases in pharmacy costs. For example, PricewaterhouseCoopers' Health Research Institute June 2014 medical cost trend report estimated that while only four (4) percent of patients use specialty drugs, those medications account for 25 percent of total drug spending nationwide. Further, a recent report by Avalere Health, commissioned by America's Health Insurance Plans, assessed the impact of breakthrough therapies on federal and state spending for Medicare, Medicaid, and the Exchange marketplace estimated that more than 5,400 medications are in the drug pipeline. With a wide range of specialty medications expected to come to market over the next several years, OPP and the HPC may want to examine how increases in prescription drug spending will affect the Commonwealth's ability to meet the cost benchmark.

Thank you for the opportunity to offer comments on the proposed changes to 958 CMR 3.101 and 958 CMR 3.400. If you or your staff have any questions or require any additional information, please do not hesitate to contact me at 617-338-224 x102.

Sincerely,



Eric Linzer
Senior Vice President, Public Affairs & Operations