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December 22, 2013

Lois Johnson
General Counsel
Health Policy Commission
Two Boylston Street, 6th Floor
Boston, MA 02116

Via Electronic Mail

Re: Proposed Updates to Office of Patient Protection Regulation 958 CMR 3.000 – Health Insurance Consumer Protection

Dear Ms. Johnson:

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates the opportunity to comment on the proposed amendments to the Code of Massachusetts Regulations (CMR) issued by the Massachusetts Health Policy Commission (the Commission) to implement certain health insurance consumer protections required under the federal Affordable Care Act and related Massachusetts state laws (the Proposed Rules).¹

PhRMA is a voluntary nonprofit organization representing the country's leading research-based pharmaceutical and biotechnology companies, which are devoted to inventing medicines that allow patients to lead longer, healthier, and more productive lives. PhRMA companies are leading the way in the search for cures.

PhRMA believes that robust health insurance coverage with a wide-range of therapeutic classes of prescription drugs is vital to ensure that all patients have meaningful access to the medications that they need. A transparent and easy-to-navigate internal grievance process, affording enrollees an opportunity to challenge an adverse determination by a carrier that a particular treatment is "not medically necessary" or is "experimental or investigational", is a critical safeguard to ensure access to high-quality, medically necessary care. The medical needs of the most vulnerable enrollees can be assessed only on a case-by-case basis, and a transparent utilization review process and comprehensive internal grievance procedures are indispensable to ensure that carriers make individualized coverage determinations and do not inappropriately deny enrollees access to needed care.

¹ Available at <http://www.mass.gov/anf/docs/hpc/opp/20131120-opp-reg-proposed-amendments-all-redlined-version-v1.pdf>.

Pharmaceutical Research and Manufacturers of America

Therefore, PhRMA broadly supports the consumer protections established in the Affordable Care Act (“ACA”) and related Massachusetts state laws and commends the Commission for undertaking this rulemaking to update its internal grievance and external review procedures consistent with those requirements. At the same time, PhRMA believes that even more transparency and oversight related to carriers’ utilization review activities are needed to ensure that the procedures adequately protect the most vulnerable patients. Specifically, PhRMA urges the Commission to: (1) require each carrier to adopt a written document describing its utilization review activities and procedures and to provide a copy of document to the Commission and to members of the public; and (2) hold carriers responsible for ensuring that their utilization review organization contractors comply with the requirements set forth in 958 CMR 3.000. PhRMA also urges the Commission to establish similar transparency requirements and procedural protections for prescription drug benefits, including (1) requiring carriers to make plan formularies and lists of primary care and specialty care providers available to enrollees and prospective enrollees so that individuals can select a plan that is appropriate for them, and (2) specifying standards for a medical exceptions process that provides coverage for medically necessary drugs that are not on a plan’s formulary. Each of these suggestions is described in more detail below.

I. The Commission Should Require Even More Transparency and Accountability for Carriers’ Utilization Review Activities.

PhRMA strongly believes that transparency and accountability regarding carriers’ utilization review activities are crucial to ensure that enrollees have a meaningful opportunity to appeal denials of medically necessary treatments and to ensure that plans do not use utilization review to prevent enrollees with significant health care needs from accessing the life-saving treatments that they need.

A. The Commission Can Build on Proposed Transparency Requirements for Utilization Review.

PhRMA applauds the numerous amendments included in the Proposed Rules that require carriers and utilization review organizations to provide more detailed information to enrollees regarding utilization review decisions and internal appeals of those decisions.² In particular, PhRMA supports the Proposed Rules’ requirement that among other information, each written resolution of an internal grievance that results in an “adverse determination” against the enrollee contain, *at a minimum*:

² *E.g.*, Proposed 958 Mass. Code Regs. 3.101(3) (requiring utilization review criteria and medical necessity criteria to be made available to the Office of Patient Protection and to members of the public upon request and at no charge); Proposed 958 Mass. Code Regs. 3.301(3) (requiring the carrier or utilization review organization to provide certain additional information where the carrier or utilization review organization considers, generates, or relies upon new evidence or a new rationale for its decision); Proposed 958 Mass. Code Regs. 3.307(2),(3) (revising the specific information that must be included as part of the clinical justification for a final adverse determination).

- explain “in a reasonable level of detail the specific reasons the review found that the medical evidence does not support a finding of medical necessity,”
- reference to and copy of any applicable clinical practice guidelines and medical necessity criteria that were used in making the decision, and
- provide a summary of the reviewer’s professional credentials and a certification that the reviewer has no conflict of interest and is actively practicing in the same or similar specialty as the professional who typically treats the medical condition.³

PhRMA similarly supports the Commission’s efforts to increase transparency by enhancing carriers’ obligation to report information related to their internal grievance procedures to the Office of Patient Protection or the Commissioner of Insurance and to make certain information available to the public. For example, PhRMA believes that the Proposed Rule requiring carriers to make their “utilization review criteria and medical necessity criteria and protocols” available to the Office of Patient Protection and to members of the public “upon request and at no charge,”⁴ will serve as an important safeguard to ensure that carriers do not use utilization review to inappropriately deny coverage of medically necessary care. PhRMA also supports the Proposed Rule requiring carriers to annually report the total number of filed grievances, the number of grievances which resulted from an adverse determination, the outcome of those grievances, and the percentage of insureds who filed internal grievances with the carrier, among other information.⁵ That information will be critical for the Commission to exercise meaningful oversight over carriers’ compliance with internal grievance procedures specified in the CMR and to ensure that those procedures do in fact provide a meaningful opportunity for individual enrollees to obtain coverage of—and thus access to—medically necessary care.

However, PhRMA also believes that the Commission should build on the amendments in the Proposed Rules to further increase the transparency of a carrier’s utilization review activities. Specifically, PhRMA encourages the Commission to require all carriers to establish a written utilization review program that describes all of their utilization review and internal appeals activities and procedures, identifying which activities are performed by the carrier and which activities are performed by a utilization review organization, and to make that information available to the Office of Patient Protection and to members of the public upon request at no charge. PhRMA respectfully suggests that one way to achieve this would be as follows:

- (1) Amend the Proposed 958 Mass. Code Regs. 3.101: Carrier’s Medical Necessity Guidelines, by adding the phrase “and Utilization Review Program Description” to the title and by adding a new paragraph (4)—

³ Proposed 958 Mass. Code Regs. 3.307(2).

⁴ Proposed 958 Mass. Code Regs. 3.101(3).

⁵ Proposed 958 Mass. Code. Regs. 3.600(1)(d).

“(4) (a) Each carrier shall implement a written utilization review program that describes all utilization review activities and procedures, both performed by the carrier and delegated to a utilization review organization, if any, for:

- (i) The filing of benefit requests;
- (ii) The notification of utilization review and benefit determinations; and
- (iii) The review of adverse determinations in accordance with the standards codified in 45 C.F.R. 147.136 and 958 CMR 3.000 and any other applicable federal or state laws or regulations.

(b) The written utilization review program document shall describe at least the following:

- (i) Guidelines used to evaluate the medical necessity of services as described in paragraph (1);
- (ii) Data sources and clinical review criteria used in decision-making;
- (iii) Mechanisms to ensure consistent application of clinical review criteria and compatible decisions;
- (iv) Data collection processes and analytical methods used in assessing utilization of health care items and services;
- (v) The organizational structure that periodically assesses utilization review activities and reports to the carrier’s governing body; and
- (vi) The staff position functionally responsible for day to day program management.

(c) Carriers shall make the written utilization review program described in this paragraph (4) available to the Office of Patient Protection and to members of the public upon request and at no charge.

PhRMA believes that it is also important for individuals to receive a copy of the carrier’s written utilization review program upon enrollment in a plan issued by that carrier. PhRMA respectfully requests that the Commission amend Proposed 958 Mass. Code Regs. 3.600: Reporting Requirements:

by inserting after the subparagraph (1)(e)(6), a new subparagraph (7)—

“ 7. the written utilization review program document described in 958 CMR 3.101(4);”

and by renumbering the current subparagraph (7) as subparagraph (8).

B. The Commission Should Hold Carriers Accountable for Activities by Utilization Review Organizations.

PhRMA also commends the Commission for its clear recognition that it is equally important for the Commission to exercise oversight over the utilization review organizations that carry out utilization review activities under contract with or on behalf of carriers. PhRMA appreciates that utilization review organizations also must comply with amendments in the Proposed Rules related to enrollees' right to an internal grievance process, the information that must be provided regarding the internal grievance process, the time limits for review of an internal grievance, the review process for internal grievances, and the information that must be provided in each written resolution of an adverse determination.⁶

To further safeguard consumers, the Commission also could task carriers with monitoring their utilization review organizations to ensure compliance with the requirements in the Proposed Rules. Specifically, PhRMA respectfully asks the Commission to consider adding a new paragraph (4) to the Proposed 958 CMR 3.300: Right to an Internal Grievance as follows:

“(4) A carrier shall be responsible for monitoring all utilization review activities and reviews of internal grievances performed by a utilization review organization on its behalf or under contract with such carrier and for ensuring that all applicable requirements provided by federal law, federal regulation, state law, and state regulation for such activities and procedures are met.”

II. The Commission Should Adopt Additional Transparency Requirements Regarding the Scope of Covered Benefits.

In addition to requiring more transparency related to utilization review activities, PhRMA also believes it is critical for prospective enrollees to have sufficiently detailed information about the scope of covered benefits, any cost-sharing obligations, and the quality of care covered under each plan so that individuals can meaningfully compare plans and select the plan that provides the most appropriate coverage. PhRMA recognizes that the ACA and federal “Summary of Benefits and Coverage” regulations require plans to disclose certain information to prospective enrollees or applicants,⁷ but PhRMA urges the Commission to require carriers to provide more detailed information about the scope of covered benefits to prospective enrollees.

For example, PhRMA believes that in addition to information about a plan's use of a formulary in its prescription drug benefit and the cost-sharing structure of that formulary, individuals need information about specific drugs to be able to meaningfully compare plans. An individual whose chronic condition is well-managed on a given medication should not be forced to change medications or incur excessive cost sharing because he

⁶ See generally Proposed 958 Mass. Code Regs. 3.300-.314.

⁷ 42 U.S.C. § 300gg-15; 45 C.F.R. § 147.200.

or she was unable to determine that the plan did not cover or prefer that drug. PhRMA therefore recommends that the Commission require each carrier to provide full formulary information, on a plan-by-plan basis, to the Office of Patient Protection and to make this information available to consumers on the carrier's website, similar to the formulary information collected and made public for Medicare Part D plans, and to update the published information within 24 hours of any change.

Similarly, for many prospective enrollees, knowing whether a particular specialty provider is "in-network" is an important factor in their selection of a plan. Although PhRMA appreciates that the Commission requires carriers to provide a list of providers, organized by specialty and by location, that are in the carrier's network "upon enrollment" and to the Office of Patient Protection,⁸ that does not help a prospective enrollee select the appropriate plan in the first place. PhRMA encourages the Commission to require all plans to list participating primary care and specialty providers on their own websites so that such information is available to enrollees prior to enrollment.

Accordingly, PhRMA recommends that the Commission revise the Proposed 958 CMR 3.600: Reporting Requirements to add reporting requirements for carriers to provide full formulary information and lists of providers to the Office of Patient Protection and to make such information available to prospective enrollees on carriers' websites.

III. The Commission Should Adopt Specific Standards for a Medical Exceptions Process for the Prescription Drug Benefit.

While PhRMA understands that these Proposed Rules are intended to primarily regulate utilization review determinations and related internal grievance and external review processes for all health care services, which may include prescription drugs, PhRMA believes that it is also important to establish a parallel set of standards for carriers to provide a medical exceptions process for their prescription drug benefits. Indeed, federal regulations implementing the ACA's "essential health benefits" (EHB) require all plans offering the EHB to have procedures in place "to allow enrollees to request and gain access to clinically appropriate drugs not covered by the health plan."⁹ PhRMA therefore encourages the Commission to specify that carriers must have in place a two-step medical exceptions process to allow enrollees to gain access to clinically appropriate drugs that includes both an internal and external review. To ensure the exceptions process does in fact provide meaningful access to such drugs, PhRMA further encourages the Commission to require plans to continue to cover any drug approved through the medical exceptions process as long as the enrollee continues to need the drug and remains enrolled in the plan. The Commission also should prohibit plans from applying differential cost-sharing to prescription drugs approved through the

⁸ See 958 Mass Code Regs. 3.600(e).

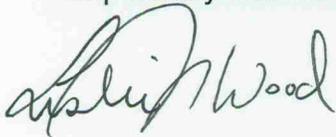
⁹ 45 C.F.R. § 156.122(c).

medical exceptions process; instead, the plan should provide coverage for approved exceptions with the same cost-sharing as other preferred drugs on the plan's formulary.

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We thank you for your consideration of these comments on the draft Proposed Rules. We urge the Commission to revise its proposed rules to further protect health insurance consumers in Massachusetts. We look forward to working with the Commission as these health insurance reforms are implemented. Please feel free to contact me if you have any questions regarding these comments.

Respectfully submitted,

A handwritten signature in black ink that reads "Leslie N. Wood". The signature is written in a cursive style with a large, looped initial "L".

Leslie N. Wood