



December 23, 2013

David Seltz, Executive Director  
Health Policy Commission  
Two Boylston Street, 5<sup>th</sup> Floor  
Boston, MA 02116

Marylou Sudders, Chair  
Quality Improvement and Patient Protection Committee  
Health Policy Commission  
Two Boylston Street, 5<sup>th</sup> Floor  
Boston, MA 02116

Jennifer Bosco, Director  
Office of Patient Protection  
Health Policy Commission  
Two Boylston Street, 5<sup>th</sup> Floor  
Boston, Ma 02116

**Re: 958 CMR 3.000 – Health Consumer Protection**

Dear Executive Director Seltz, Chairwoman Sudders and Director Bosco:

Thank you for the opportunity to share McKesson's perspective on the proposed *958 CMR 3.000 Health Insurance Consumer Protection* regulations. We support and commend the Massachusetts Health Policy Commission's ongoing efforts to protect patient safety and improve health care quality.

On December 16, I testified before the Quality Improvement and Patient Protection Committee ("the Committee") regarding our concerns with disclosure of medical necessity criteria to the general public. McKesson appreciates the opportunity to submit additional detailed comments to the Committee on the proposed regulations. As recommended by the Committee, we are submitting specific suggested language changes below.

#### **ABOUT MCKESSON**

For 180 years, McKesson has led the industry in the delivery of medicines and healthcare products. As the largest health IT company in the world, we are actively engaged in the transformation of healthcare from a system burdened by paper to one empowered by interoperable electronic solutions that improve patient safety, reduce the cost and variability of care and advance healthcare efficiency. McKesson has decades of experience serving the health IT needs of the largest and most diverse provider base in the industry, including 50 percent of all health systems, 77 percent of health systems with more than 200 beds, 20 percent of all physician practices and 25 percent of home care agencies, which support more than 50,000 home care visits annually. We process billions of financial healthcare transactions annually among physicians, hospitals, pharmacies, insurers and financial institutions, and provide care and claims

management solutions to most of America's health insurance companies. McKesson has over 600 employees in Massachusetts.

## **ABOUT INTERQUAL**

In Newton, Massachusetts more than 170 employees work on the development and support of InterQual®, an industry-leading solution to help payers and providers collaborate for better, safer, healthcare at lower costs. The InterQual criteria are designed to help determine the clinical appropriateness of proposed care, also known as medical necessity. InterQual provides medical evidence to payers and providers to align decision making, improve patient outcomes and drive greater efficiency.

It is important to note that final decisions around clinical or payment determinations rest with the provider or licensing payer and that the criteria themselves are intended solely for use as screening guidelines with respect to the medical appropriateness of healthcare services.

InterQual has been available since 1976 and is widely regarded as the leading clinical criteria in the market with thousands of licensees, including

- 4,100 hospitals;
- 300 payer organizations;
- Centers for Medicare and Medicaid Services (CMS);
- Eight Medicare Administrative Contractors and
- U.S. Department of Veteran Affairs.

InterQual criteria are developed by a dedicated team of McKesson clinicians, using a rigorous, evidence-based process, in conjunction with an independent national panel of more than 650 clinical experts. The criteria reflect the input of multiple experts in a particular clinical specialty, whose credentials are carefully reviewed every two years. In addition, clinicians are screened for potential conflicts of interest to prevent bias. InterQual developers receive comprehensive training in evidence based medicine to ensure that the criteria reflect the best medical literature available. McKesson uses the same multi-step standardized annual development process for its medical, surgical and mental health/substance use disorders criteria. The InterQual criteria are used by our clients in hard copy books, as well as through our patented software.

Each year, InterQual is updated through a comprehensive process that includes:

1. Identification of content areas for review based upon feedback from providers, patients and health plans,
2. A critical appraisal of relevant new and updated clinical literature, and
3. An iterative process of external review by panels of independent, practicing and credentialed clinicians from the relevant specialties.

## **TRANSPARENCY OF INTERQUAL**

InterQual provides an evidence based foundation to enable sharing of clinical decisions between payer, provider and patient. We remain committed to the appropriate disclosure of our clinical content and support the following mechanisms to achieve this today:

1. Our license agreements with our customers specify that relevant clinical criteria can be shared with both providers and patients in the event that a specific request does not meet the criteria the payer is using for a particular treatment or diagnostic decision. This provision allows for complete transparency of the criteria relevant to a given patient and their specific circumstance.
2. Where required, we have submitted the InterQual criteria, in its entirety, to government regulators for the purposes of disclosure, and review by providers with appropriate confidentiality protections. For example, we have worked with the State of Rhode Island to allow medical directors of all hospitals in the state to securely access InterQual and comment prior to our annual release. Most recently, we submitted the InterQual mental health/substance use criteria to the State of Connecticut for certification. After carefully evaluating the criteria, McKesson Health Solutions, through the InterQual criteria, was determined to be a qualified vendor for mental health/substance use clinical review criteria through 2015 in that state.
3. In addition, we have developed a summary of InterQual and its rigorous process of development (outlined above) which may be submitted to regulators, and/or posted by our customers on their websites.
4. Finally, we are committed to providing access to providers who seek to review and comment on InterQual, provided that these providers conduct their review in a manner that protects the confidentiality of our intellectual property. It is important to note that input from independent providers is not included in the criteria unless it is supported by the medical evidence and by our panel of national clinician reviewers.

## **PROTECTION OF INTELLECTUAL PROPERTY AND DISCLOSURE TO “THE PUBLIC”**

The process of developing, maintaining and updating the InterQual criteria represents a significant investment in intellectual property. We do not believe that providing the InterQual criteria in its entirety to members of the public is appropriate for three primary reasons:

1. We believe that making the body of InterQual criteria available publicly would unfairly deprive us of the value of intellectual property that took nearly 40 years, thousands of man hours and millions of dollars to develop. Where we have provided the content to regulators or providers we have done so in a way that protects InterQual from inappropriate and unlawful disclosure of our valued proprietary information.
2. McKesson already actively seeks the input of the provider community in the development of InterQual. As has been noted, the development of InterQual includes a rigorous process of external review by certified, unbiased clinicians. We are happy to engage with additional clinicians to provide them access to InterQual for the purpose of review and comment, subject to provisions which maintain the confidentiality of our proprietary information. We continue to

strongly support the intent of the legislation to improve healthcare quality and ensure patient protection, but we do not believe that public disclosure will contribute to these goals.

3. We are particularly concerned about disclosing the criteria in its entirety to entities who may either seek to compete with our clinical criteria, and/or unduly influence the criteria according to a particular bias or for their own pecuniary gain. We take great pride in the fact that InterQual is rigorously developed, evidence based, and unencumbered by financial bias.

### **PROPOSED CHANGES TO [DRAFT] 958 CMR 3.000**

For the reasons outlined above, we respectfully propose the following broad changes to [DRAFT] 958 CMR 3.000:

1. Require disclosure (at no cost) of utilization review and medical necessity criteria to the Office of Patient Protection only.
2. Require carriers to document in summary form, the rigorous development process of medical necessity and utilization review criteria, and post such documentation on its website.
3. Require carriers to document applicable medical necessity or utilization review criteria in every adverse determination notice.
4. Require the Office of Patient Protection to protect confidential proprietary information.

To codify these changes, we suggest the following specific language changes:

#### **3.101 (3):**

*“Utilization review criteria and medical necessity criteria and protocols shall be made available by the carriers to the Office of Patient Protection with appropriate confidentiality protections.”*

#### **3.101 (4): (new subsection)**

*“An overview of the process of the development of the utilization review criteria and medical necessity criteria, consistent with 3.101 (1) above and 3.600 (1) (e) (4) below shall be maintained by every carrier and posted publicly to the carrier’s website.”*

#### **3.307 (3) (d): (new subsection)**

*“Relevant claim-specific medical necessity criteria applicable to the specific adverse determination”*

#### **3.600 (4):**

*“The confidentiality of any information about a carrier or utilization organization which, in the opinion of the Office of Patient Protection in consultation with the Division of Insurance, is proprietary in nature shall be protected.”*

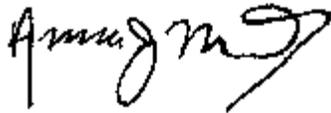
## SUMMARY

InterQual is a market leading clinical criteria which has been developed and honed over four decades. We believe strongly that the use of rigorously developed, unbiased, evidence based criteria promotes clinical quality, improved outcomes and greater efficiency in healthcare. Moreover, we support judicious and protected disclosure of this clinical information to create an open and transparent dialogue between payers, providers and patients.

McKesson has a track record of collaborating with regulators to achieve these goals and we welcome the opportunity to work with The Commission, The Office of Patient Protection and other appropriate regulators in Massachusetts.

We appreciate the forum to offer our perspective and support the Committee's efforts to improve healthcare quality and patient protection.

Sincerely,

A handwritten signature in black ink, appearing to read "A. Mitus". The signature is stylized and cursive.

A. Jacqueline Mitus, MD  
Senior Vice President, Clinical Development and Strategy  
McKesson Health Solutions

cc: Lois Johnson, Health Policy Commission  
Kevin Beagan, Division of Insurance