



Members of the Medical Services Board  
Colorado Department of Health Care Policy & Financing  
1570 Grant Street  
Denver, CO 80203

August 9, 2023

RE: Revision to the Medical Assistance Act Rule concerning HB23-1130 and HB23-1183  
Implementation, Section 8.800.1 and 8.800.7, MSB 23-04-25-B

Dear Members of the Colorado Medical Services Board:

We, the undersigned, represent [Brain Health Colorado](https://www.brainhealthcolorado.org), a diverse group of Colorado-based mental health, patient advocacy, and community organizations. Our shared goal is to help destigmatize mental illness in Colorado and modernize our mental healthcare system so that patients can enjoy quick and easy access to life-saving medication. Members of the Coalition who supported enactment of HB 23-1130 included Aurora Mental Health, Ethiopian Community of Colorado, Rocky Mountain Indian Chamber of Commerce, Mental Health Colorado, KBNO Radio Station, Rocky Mountain NAACP State Conference, Colorado Professional Firefighters AFL-CIO, and the Wezesha Dada Center.

We are writing to the Colorado Department of Health Care Policy & Financing (HCPF) to provide comments on Rule MSB 23-04-25-B, which aims to implement HB23-1130 and HB23-1183, legislation recently passed by the Colorado legislature to improve and accelerate access to prescription drugs for serious mental illness (SMI). We appreciate the expeditious work that Colorado HCPF has already done to implement these two pieces of legislation.

In general, Brain Health Colorado appreciates the way in which the state proposes to implement the new statutes, but we are concerned that the proposed regulatory text may introduce some unintended ambiguities and undermine the intent, in particular, of HB23-1130.

Our main concern relates to potential ambiguity in the proposed regulatory text that establishes a new 90-day time frame for HCPF to determine whether a new prescription drug for the treatment of SMI will be a preferred or non-preferred drug.

The proposed regulatory text requires that “preliminary coverage reviews” for new SMI drugs occur within 90 days of their FDA approval. As you know, Colorado already has a regulation (10 C.C.R. 2505-10, Section 8.800.16.B) requiring the state to conduct a “*preliminary evaluation*” of a new drug within 30 days from when the drug becomes available on the market (emphasis added). This same regulation requires that, upon completion of this preliminary evaluation, the state must designate the new drug as preferred or non-preferred, and that designation must remain in place until the drug class is officially reviewed again (which occurs at least annually).

The proposed regulation's reference to "preliminary coverage reviews" raises some concerning ambiguities, since the proposed regulation does not define "coverage reviews" and does not make any reference back to the "preliminary evaluation" provision of Section 8.800.16.B.

Given the clear intention of the legislature to accelerate coverage and access for new SMI drugs for Coloradans, we suggest some clarification to the proposed text in order to ensure that the new regulation accelerates the coverage process.

In particular, HCPF should clarify that the proposed regulatory requirement to review a new SMI drug would require that a decision (as opposed to just the instigation of a decision process) to designate the drug as preferred or non-preferred must be reached within 90 days following FDA approval and take effect immediately. With such clarification, the two provisions (8.800.16.B and 8.800.7.D) would work together: HCPF would initiate the "preliminary evaluation" within 30 days pursuant to 8.800.7D, and, pursuant to HB 23-1130, would also perform an official "review for coverage" within 90 days.

It is essential, given the legislature's intent in passing HB23-1130, that the proposed regulations not introduce any ambiguities with respect to the coverage procedures and timelines for SMI drugs that would offset any benefit for patients derived from the new statute. We are happy to provide further comment or input on the best way to achieve this goal.

Finally, with respect to the implementation of both laws, we would note that the proposed definition for "serious mental illness" at 8.800.1KK does not include a reference to the Diagnostic and Statistical Manual of Mental Disorders (DSM). In listing diseases that qualify as SMI, the statute includes a specific reference that the diseases are to be understood "as defined by the American Psychiatric Association in the most recent version" of the DSM. Our understanding is that the underlying statute should still govern the interpretation of the regulation, and therefore the disease definitions used would be those in the most recent edition of the DSM. That said, adding a reference to the DSM to the regulatory text would clarify the regulation's meaning and remove any potential ambiguity around whether the HCPF intended to depart from the statute's intended definitions.

We appreciate the expeditious work that Colorado HCPF has already done to implement these two pieces of legislation and are happy to expound on our comments as needed.

Sincerely,

BRAIN HEALTH COLORADO  
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