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Miller Senate Office Building, 3 East
Annapolis, MD 21401

**RE: SB 441 - Maryland Medical Assistance Program – Prescription Digital Therapeutics
Position: Support with Amendments**

Dear Chair, Vice-Chair and Members of the Committee:

The Maryland Psychological Association, (MPA), which represents over 1,000 doctoral level psychologists throughout the state, asks the House Health and Government Operations Committee to **FAVORABLY report on SB 441 with the Amendment below**. Prescription Digital Therapeutics are software-based treatments for medical, mental health, and substance use disorders. Prescription Digital Therapeutics must be tested for safety and efficacy in clinical trials and then evaluated and cleared for use by the Food and Drug Administration. The FDA regulation which created this prescription device category (21 CFR Sec. 801.109(a)(2)) provides that a prescription device must be “sold only to or on the prescription *or other order of such practitioner* for use in the course of his professional practice.”

The MPA recognizes the Committee’s leadership with regard to Prescription Digital Therapeutics. The current bill, however, precludes the vast majority of Maryland Medical Assistance clients with substance use disorders and depression from accessing these treatments because they are not receiving services from prescribing practitioners (e.g., physicians, physician assistants, nurse practitioners). The proposed amendment ensures that Maryland Medical Assistance clients who are in treatment with psychologists and other licensed health care professionals can access these effective treatments via an appropriate Order, consistent with FDA regulations.

The suggested amendment would be inserted on p.2, line 13:

4) CAN BE DISPENSED ONLY IN ACCORDANCE WITH A PRESCRIPTION [.] OR ORDER PURSUANT TO THE REQUIREMENTS UNDER 21 C.F.R. § 801.109 OR ANY SUCCESSOR REGULATION.

Thank you for considering our comments on SB 441. If we can be of any further assistance as the Senate Finance Committee considers this bill, please do not hesitate to contact MPA’s Legislative Chair, Dr. Pat Savage at mpalegislativcommittee@gmail.com.

Respectfully submitted,

Rebecca Resnick, Psy.D.

Rebecca Resnick, Psy.D.
President

R. Patrick Savage, Jr., Ph.D.

R. Patrick Savage, Jr., Ph.D.
Chair, MPA Legislative Committee

cc: Richard Bloch, Esq., Counsel for Maryland Psychological Association
Barbara Brocato & Dan Shattuck, MPA Government Affairs