AMCP
Optimizing medicine.
Improving lives.

REGULATORY **ACTION ITEMS:**

Prescription Digital Therapeutics

Prescription digital therapeutics (PDTs) are an emerging treatment option for a variety of conditions. Currently, Medicare is unable to cover these products because they do not fit into one of the existing statutorily-defined benefit categories. Medicaid plans are often unsure if they can cover PDTs without a benefit category. While AMCP believes that the best solution to enable coverage is to create a new benefit category for PDTs through legislation, below are recommendations federal agencies can enact now to improve the coverage landscape for these products.

- **The Food & Drug Administration (FDA) should issue a definition of Prescription Digital Therapeutics (PDTs), as well as a definition of digital therapeutics.**
  PDTs are FDA-authorized, software-based therapies that deliver a clinical benefit to patients, either alone or in combination with other therapies. Like other prescription therapies, PDTs are put through rigorous testing and randomized clinical trials before they are authorized by FDA. Yet, PDTs are not explicitly defined by FDA, leading to confusion over the differences between prescription digital therapeutics, non-prescription (or "over-the-counter") digital therapeutics, and other digital health and wellness applications. Separate FDA-issued definitions for PDTs and digital therapeutics will distinguish safe and effective prescription products that receive a rigorous FDA review from those that undergo a less comprehensive review.

- **The Center for Medicaid and CHIP Services (CMCS) should issue guidance clarifying state Medicaid programs' authority to cover PDTs.**
  Currently, the Veterans Affairs Health System and a small share of state Medicaid programs provide the only public coverage for PDTs in the United States. Given the lack of federal regulatory guidance on the ability of these programs to cover PDTs, Medicaid plans have been hesitant to adopt coverage. By clarifying state Medicaid programs' ability to issue coverage for PDTs, CMCS will eliminate confusion and expand access to PDTs for some of the nation's most vulnerable patients.

- **The Centers for Medicare and Medicaid Services (CMS) should develop a comprehensive Healthcare Common Procedure Coding System (HCPCS) coding practice for PDTs.**
  There are approximately a dozen FDA-authorized PDTs available to patients. However, the lack of a separate Medicare and Medicaid benefit category for PDTs has culminated in a patchwork of reimbursement strategies and coding practices for PDTs nationwide. By asking CMS to implement a HCPCS coding system that creates individual product codes for PDTs, existing administrative barriers to coverage are addressed while patients gain expanded access to these innovative therapies. A workable HCPCS coding system recognizes the unique qualities that differentiate each PDT product, which is achieved by establishing an individual code for each FDA-authorized PDT.

REGULATORY **ACTION ITEMS:** *(cont.)*

Prescription Digital Therapeutics

- **CMS should issue a Request for Information (RFI) on industry practices and experiences in covering PDTs under HCPCS Level II Code A9291.**

  Although a comprehensive, workable coding practice for PDTs has yet to be implemented, CMS has taken several steps to simplify the reimbursement process for PDTs. In response to the authorization of two PDTs with cognitive behavioral components, the agency established a Level II HCPCS code, A9291, which covers prescription digital behavioral therapies. Currently, CMS assigns this code to PDTs regardless of their indications, ignoring that FDA-authorized PDTs exist to treat several additional conditions, including amblyopia, diabetes, and pulmonary disease. By releasing an RFI on payer experiences in covering PDTs under HCPCS Level II Code A9291, CMS will establish a repository for gathering real world-evidence on the difficulties payers face in reimbursing the existing array of PDTs under a single code. The publication of an RFI provides a forum for payers to suggest improvements to the current coding process.