



December 16, 2019

The Honorable Diana DeGette  
The Honorable Fred Upton  
U.S. House of Representatives  
Committee on Energy and Commerce  
United States Congress  
Washington, DC 20515

***Re: 21<sup>st</sup> Century Cures 2.0***

Dear Representatives DeGette and Upton:

The Academy of Managed Care Pharmacy (AMCP) appreciates the opportunity to submit feedback for consideration in the legislative process to implement “Cures 2.0.” In December 2016, AMCP applauded the passage of the 21<sup>st</sup> Century Cures Act as it included many provisions that will directly improve the health of Americans, from prompting new cures for cancer to combating opioid addiction. Our feedback for Cures 2.0 will focus on better access to innovative therapies through codification of existing FDA guidance for the communication of health care economic information (HCEI) in law and digital therapeutics (dTx).

AMCP is the nation’s leading professional association dedicated to increasing patient access to affordable medicines, improving health outcomes and ensuring the wise use of healthcare dollars. Through evidence- and value-based strategies and practices, the Academy’s 8,000 pharmacists, physicians, nurses and other practitioners manage medication therapies for the 270 million Americans served by health plans, pharmacy benefit management firms, emerging care models and government.

In 2016, AMCP supported the inclusion of Section 3037 in the 21<sup>st</sup> Century Cures Act that modernized Section 114 of the Food and Drug Administration Modernization Act (FDAMA114) of 1997. FDMA Section 114 was enacted to authorize the communication of HCEI between biopharmaceutical companies and formulary committees or similar entities. Section 3037 of the 21<sup>st</sup> Century Cures Act helps make it possible for health plans and other payers to get the product information they need to determine the value of new and old medicines in improving patient outcomes. This section took an important step towards creating a value- and outcomes-based health care system that will give patients the medicines they need while ensuring the wise use of health care dollars. However, there are still improvements needed to address more timely and proactive communications between biopharmaceutical manufacturers and population health decision-makers to ensure patient access to innovative, high cost medications.

HCEI has long been valued by population health decision-makers (e.g. payers, provider sponsored health plans, pharmacy benefit managers, accountable care organizations, integrated delivery networks) that are responsible for formulary decision making for its assistance in evaluating the benefits and costs of drugs and health technologies. The ability of health care decision-makers and biopharmaceutical manufacturers to exchange HCEI is increasingly important as drug costs rise and as more specialty products become available. In January 2017, the FDA issued a draft guidance on HCEI communication between pharmaceutical manufacturers and payers. These efforts provide greater clarity regarding permitted manufacturer communications for HCEI, yet the impact remains unclear.

In 2016, AMCP convened a multi-stakeholder forum focusing on the creation of a safe harbor for the exchange of HCEI and clinical information prior to FDA approval, known as Preapproval Information Exchange (PIE). Recommendations from this forum were published in the *Journal of Managed Care and Specialty (JMCP)* in January 2017.<sup>1</sup> PIE is designed to improve patient access to emerging pharmaceuticals and devices. It allows manufacturers and population health decision-makers to proactively share certain health care economic and scientific information on products ahead of FDA approval. It applies to medications prior to FDA approval and allows biopharmaceutical manufacturers to proactively share clinical and economic information about medications in the pipeline with health care decision-makers at least 12-18 months prior to FDA approval during the forecasting and rate setting process. The exchange is limited to a narrow audience that includes only biopharmaceutical manufacturers and health care decision-makers. The need for proactive PIE communication is especially important as the health care system evolves from a fee-for-service payment system to a system rewarding quality, improved patient outcomes, and value.

While AMCP supports the 2018 FDA issued guidance on HCEI communication that expanded the scope of preapproval communications, a legal underpinning that would clarify the scope of permitted communications between pharmaceutical manufacturers and health care decision-makers is critical to increase adoption. As Congress moves forward with implementation of Cures 2.0, AMCP encourages it to include codification of PIE in law to provide population health decision-makers with the critical information they need to ensure the patient populations they serve receive access to needed and appropriate medications.

AMCP is also supportive of digital health as a significant focus of Cures 2.0, specifically as it relates to DTx. Already, digital therapies are coming to market with indications to prevent, manage, and treat conditions ranging from diabetes and asthma, to depression and substance use disorder. These products represent an important new tool for providers to address the health and wellbeing of patients facing many disease states. AMCP's goal is to ensure that patients will have access to the products that offer optimal clinical value at an affordable cost.

In September 2019, AMCP convened a group of diverse health care stakeholders to discuss the challenges and opportunities of ensuring patient access to emerging DTx which have the potential to treat a wide range of diseases and medical conditions. AMCP's Partnership Forum, "Digital Therapies: What Are They and Where Do They Fit in Pharmacy and Medical Benefits?" laid the groundwork for making coverage decisions on the therapies that many agree are on the frontier of

---

<sup>1</sup> Insert Citation: <https://www.jmcp.org/doi/10.18553/jmcp.2016.16366>

medical science. The event drew leading national players in the digital therapy space, with participants representing payers, manufacturers, employers, providers, patient advocacy groups, and government.

Questions addressed included what types of evidence are needed for coverage, along with how to evaluate safety, clinical effectiveness, comparative and cost effectiveness, data security, and interoperability. Participants also considered how pharmacy and the pharmacy benefit could play a primary role in managing and covering digital therapeutics. All findings and recommendations will be published in an upcoming issue of AMCP's *Journal of Managed Care & Specialty Pharmacy*. AMCP will share the proceedings once published and encourages Congress to utilize AMCP as a resource when developing legislation that addresses the use of DTx.

Thank you for the opportunity to provide feedback and for your consideration of our comments. AMCP looks forward to continuing work on enabling better and more timely communications between biopharmaceutical manufacturers and population health decision-makers as well as assisting efforts to advance digital health for patients. If you have any questions regarding AMCP's comments or would like further information, please contact me at 703-683-8416 or [scantrell@amcp.org](mailto:scantrell@amcp.org).

Sincerely,

A handwritten signature in black ink, appearing to read "Susan Cantrell".

Susan A. Cantrell, RPh, CAE  
Chief Executive Officer