August 02, 2024

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

***Re: 21st Century Cures 2.0 Request for Information***

Dear Representatives DeGette and Bucshon:

The Academy of Managed Care Pharmacy (AMCP) appreciates the opportunity to submit feedback for consideration on the *21st Century Cures 2.0 Request for Information*. We commend you for your efforts to build upon the success of the 2016 *21st Century Cures Act*, seeking to improve how new treatments and therapies are delivered to patients and ensuring that our health system is prepared for future challenges. We look forward to working with you to advance Cures 2.0.

AMCP's diverse membership of pharmacists, physicians, nurses, biopharmaceutical professionals, and other stakeholders leverage their specialized expertise in clinical evidence and economics to optimize medication benefit design and population health management and help patients access cost-effective and safe medications and other drug therapies. AMCP members improve the lives of nearly 300 million Americans served by private and public health plans, pharmacy benefit management firms, and emerging care models.

Our comments below detail AMCP's support for many of the provisions included in the Cures 2.0 Act of 2021. AMCP believes the legislation will help increase patient access to treatment, accelerate the development of new treatments, and decrease costs to patients and the health care system. Specifically, our priorities include:

- Increasing coverage of innovative technologies;
- Improving Medicaid access to high-cost therapies; and
- Improving requirements for post-marketing studies of drugs approved through accelerated pathways.

**New Section Suggestions**

In addition to the policies already contained in the Cures 2.0 Act, **AMCP suggests two additional policies that will improve patient access and outcomes: the Access to Prescription Digital Therapeutics Act, and the Medicaid VBPs for Patients (MVP) Act.**

*The Access to Prescription Digital Therapeutics Act (S. 723/H.R. 1458)*

This Act would create a benefit category in Medicare and Medicaid for prescription digital therapeutics (PDTs), which are prescription therapies that use software to deliver a clinical mechanism of action. PDTs are reviewed for safety and efficacy and authorized by the Food & Drug Administration (FDA). Congress should look to the available definitions and information from organizations leading the way in promoting the development, coverage, and use of digital therapeutics as it undertakes this work.[1]

The Cures 2.0 Act rightly identifies access to emerging health technologies as a critical issue for patients. AMCP is supportive of the provisions in Section 404 to codify coverage of certain breakthrough devices, as well as the report on establishing alternative pathways for innovative technology required by Section 405. However, the draft does not currently include language facilitating coverage for PDTs, some of which receive breakthrough device designation but are excluded from the coverage authorized by Section 404 due to the lack of a benefit category.

Without a benefit category, the Centers for Medicare & Medicaid Services (CMS) are unable to cover many PDTs, although they have a strong interest in doing so. In its proposed 2025 Physician Fee Schedule, CMS proposes to reimburse for "digital mental health treatment (DMHT)," which would include some PDTs, that are dispensed incident to a physician's services. This is an important step towards coverage, but it is not totally sufficient. The proposed PFS would only pay for DMHTs that use a behavioral therapy approach, leaving patients without access to PDTs that use physical therapy or neurological therapy.

**AMCP encourages the inclusion of the Access to PDTs Act in Cures 2.0 to further strengthen its benefits to patient access to innovative health technologies.**

*The Medicaid VBPs for Patients Act (S. 4204/H.R. 2666)*

The MVP Act aligns with Cures 2.0's goal of improving access to high-cost therapies, such as cell and gene therapies in Section 303, by expanding the use of value-based purchasing

[1] See: https://www.jmcp.org/doi/pdf/10.18553/jmcp.2020.19418; https://dtxalliance.org/wp-content/uploads/2021/01/DTA_DTx-Definition-and-Core-Principles.pdf

arrangements in Medicaid. Value-based purchasing arrangements, also called outcomes-based arrangements, are contracts where the total price paid is indexed to a drug's actual effectiveness. They can be structured in different ways, including installment payments or refunds, but they all base their prices on patient outcomes.

Currently, value-based purchasing is underutilized within state Medicaid programs due to complicating factors associated with the Medicaid Drug Rebate Program and Best Price Rule. Under the Best Price Rule, state Medicaid programs are entitled to match the lowest price for a drug available anywhere in the country. This led to concern among pharmaceutical manufacturers that the best price would be effectively set at zero dollars under value-based purchasing arrangements if the drug failed entirely and the purchaser was entitled to a full refund for the cost of the treatment. As a result, value-based purchasing agreements were infrequently offered even to commercial health plans.

In response, CMS implemented the Multiple Best Price Rule, which allows manufacturers to report two different best prices to CMS: one for fee-for-service (FFS) purchases, and another for value-based purchases.[2] The Multiple Best Price Rule was an important release valve, leading to greater uptake of value-based contracts with private payers. Unfortunately, it did not result in greater access for Medicaid plans and their beneficiaries.

The MVP Act seeks to fix this by codifying and clarifying the Multiple Best Price Rule, which does not contain sufficient information about the calculation of the best price under a value-based arrangement to give manufacturers confidence. The Act specifies that the best price under a value-based arrangement is the total contract price to be paid if all patient outcome benchmarks are satisfied.

Without this additional clarification, Medicaid programs will remain unable to take advantage of innovative contracting practices, leaving their patients without access to needed treatment. This is especially true in the realm of cell and gene therapies, which can cost millions of dollars. Medicaid programs are not well-equipped to absorb that cost if a drug is not effective for a patient.

**AMCP encourages the inclusion of the MVP Act in Cures 2.0 to enhance patient access to high-cost treatments.**

[2] https://www.medicaid.gov/prescription-drugs/downloads/mfr-rel-116-vbp.pdf.

**Sec. 309. Post-Approval Study Requirements for Accelerated Approval**
This provision would allow for the use of other evidence, including clinical evidence, patient registry data, or other real-world evidence, to fulfill post-approval study requirements to confirm the predicted clinical benefit of a therapy approved through an accelerated approval pathway.

*AMCP Response:*
AMCP supports this provision and the ability of drug manufacturers to submit additional evidence and data to support the confirmation of clinical benefit of therapies approved through accelerated review pathways. While we believe a provision such as this would help to encourage the collection of this valuable data, AMCP does not believe that submission of this type of evidence should be in lieu of the completion of confirmatory clinical trials, unless directed by the FDA. The completion of confirmatory trials is critical to ensure safe and appropriate access to treatments for patients, while other types of real-world evidence can help bridge the gap from the launch of a drug approved through accelerated pathways and confirmatory trial completion, which can take several years.

In addition to permitting the submission of alternative forms of evidence and data, **Congress should consider taking further action to ensure the completion of confirmatory studies for drugs approved through accelerated pathways.** As recommended by the Medicaid and CHIP Payment and Access Commission (MACPAC), Congress should require drug manufacturers to pay an additional rebate percentage on drugs approved through accelerated approval pathways until the manufacturer has completed the postmarketing confirmatory trial and received traditional FDA approval.[3] State Medicaid agencies, like other payers, have expressed concerns about the high cost for accelerated approval drugs and the uncertain benefit to patients given that these drugs are approved using surrogate endpoints that are reasonably likely to predict a clinical benefit, instead of the clinical endpoints used in traditional approval pathways. Since the Medicaid Drug Rebate Program requires coverage of all FDA-approved outpatient drugs and confirmatory trials are often delayed, "[i]ncreasing the Medicaid rebates on accelerated approval drugs until the clinical benefit has been verified strikes a balance between addressing state concerns about paying high prices for these products while maintaining access for beneficiaries."[4] The increased Medicaid rebate percentage will also serve as an incentive to drug manufacturers to complete the required postmarketing confirmatory trials.

Additionally, language should be included in Cures 2.0 that requires sunsetting of market authorization for an accelerated approval drug after a specified amount of time, set at the time of approval, in the event that confirmatory evidence is not available to the FDA for review. A formal sunsetting policy would serve to incentivize drug manufacturers to complete confirmatory studies and help to protect the FDA from external pressure to change market

[3] https://www.macpac.gov/wp-content/uploads/2021/06/Chapter-1-Addressing-High-Cost-Specialty-Drugs.pdf
[4] Ibid.

withdrawal decisions. A system for determining whether to grant extensions of this timeframe for legitimate reasons, such as needing to resolve scientific or clinical issues with confirmatory trials, should be contemplated to eliminate the possibility of withdrawing market authorization prematurely.[5]

**Sec. 104. Vaccine and Immunization Programs**

This provision would provide additional funding for vaccine awareness and strengthen the Immunization Information System.

*AMCP Response:*

AMCP supports increasing funding for vaccine awareness as it is essential to educate the public on the importance and safety of vaccines. Pharmacists and pharmacies have played a vital role in ensuring that patients receive access to the medications they need during the ongoing COVID-19 public health emergency and continue to fill an essential role in administering COVID vaccines. Given the important part that pharmacists play in community vaccination and that they are highly trained and qualified to administer vaccines, we encourage Congress to consider ways in which pharmacists can participate in and lead vaccine education endeavors.

In its efforts to increase vaccinations, both for COVID-19 and more broadly for preventable illnesses such as shingles and hepatitis A, **Cures 2.0 should include a provision requiring all appropriate preventive vaccines and their administration to be covered under Medicare Part B.** Currently, vaccines for influenza, pneumococcal disease, hepatitis B, and COVID-19, as well as other vaccines for the treatment of an injury or direct exposure to a disease, are paid for under Medicare Part B, with all other commercially available vaccines covered under Part D. In its June 2021 Report to Congress, the Medicare Payment Advisory Commission (MedPAC) recommended making this change, stating that there is a "strong rationale for moving vaccine coverage from Part D to Part B," including that more Medicare beneficiaries are enrolled in Part B than in Part D so "coverage of vaccines under Part B has the potential to reach a larger group of beneficiaries."[6] Additionally, MedPAC states that "high cost sharing in some Part D plans may prevent some beneficiaries from seeking recommended preventive vaccines," and since vaccines in Part B are traditionally covered without cost sharing, rate of vaccinations among Medicare beneficiaries should increase with Part B coverage of all vaccines. Lastly, the wide variety of health care providers who currently bill Medicare Part B means more settings where beneficiaries can receive vaccines, which should also increase vaccination rates for Medicare beneficiaries.[7]

[5] Ibid.

[6] http://medpac.gov/docs/default-source/reports/jun21_medpac_report_to_congress_sec.pdf?sfvrsn=0. Chapter 7.

[7] Ibid.

**Congress can further improve Medicare beneficiaries' access to vaccines and other important public health services by recognizing pharmacists as providers under Medicare Part B**. According to researchers from the University of California San Diego and the University of Pittsburgh, pharmacists are the most accessible health care providers in many communities, with nearly 90% of Americans living within 5 miles of a community pharmacy.[8] During the COVID-19 Public Health Emergency, pharmacists and pharmacy technicians aided the public health response by administering over 300 million COVID-19 vaccines through the Federal Retail Pharmacy Program[9] and over 42 million COVID-19 tests.[10] The Equitable Community Access to Pharmacists' Services (ECAPS) Act (H.R. 1770/S. 2477) would enable pharmacists to receive payment for essential care services under Medicare Part B, including administering vaccines, tests, or treatments for COVID-19, influenza, strep throat, and RSV. The ECAPS Act would permanently extend authorities granted to pharmacists under the COVID-19 Public Health Emergency and establish a mechanism for pharmacists to receive payment for essential care services to respond to future public health crises.

**AMCP encourages the inclusion of the ECAPS Act in Cures 2.0 to ensure that Medicare patients receive enhanced access to essential care services through their community pharmacy.**

**Sec. 201. Educational Programs and Training for Caregivers**

This section proposes to establish a grant program through HHS to fund education and training for caregivers to improve medication adherence, among other things, for their care recipients to complement, but not compete with, clinical visits.

*AMCP Response:*

**AMCP supports the creation of this caregiver education grant program and recommends including medication therapy management (MTM) programs in the list of eligible programs to receive grant funding.** Managed care organizations (MCOs) play an important role in care coordination for their members and are well positioned to conduct the trainings funded by this provision. Specialty pharmacies also have a strong interest in improving medication adherence to prevent the negative patient outcomes associated with nonadherence and often have staff that administer at-home injections and infusions.

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[8] Berenbrok, L. et al. (2022). *Access to community pharmacies: A nationwide geographic information systems cross-sectional analysis*. Journal of the American Pharmacists Association, Vol. 62, Iss. 6. https://doi.org/10.1016/j.japh.2022.07.003.

[9] https://archive.cdc.gov/www_cdc_gov/vaccines/covid-19/retail-pharmacy-program/index.html.

[10] https://www.pharmacist.com/APhA-Press-Releases/study-pharmacy-teams-delivered-more-than-270-million-covid-19-vaccinations-averting-more-than-1-million-pandemic-deaths.

MTM programs in Medicare Part D provide a promising model that private plans can adopt to increase patient and caregiver education. MTM programs are typically performed by a pharmacist as part of a care management plan and include education for patients and caregivers on medication administration and adherence. These efforts are increasingly important as specialty drugs represent a growing share of prescriptions and may have more complex administration requirements, such as injection, compared to other treatments. A comprehensive 2019 review of the available literature on MTM programs published in the *Journal of Managed Care + Specialty Pharmacy* found that they were associated with an increase in medication adherence.[11] Other MTM services, such as the completion of comprehensive medication reviews (CMRs), have been shown to be valuable to beneficiaries and to the Medicare program. A CMS-commissioned study of the MTM program found that "MTM enrollees who received CMRs were more likely to experience increases in medication adherence and improvements in quality of prescribing."[12] Although there are some small-scale MTM efforts within privatized plans, it has not seen widespread uptake.

Caregiver education tailored to MTM programs and CMRs could improve patient health outcomes by promoting medication adherence and avoiding adverse drug events, particularly among minority groups. A recent study published in the *Journal of Managed Care + Specialty Pharmacy* demonstrated disparities in the completion of CMRs based on patients' racial and ethnic identity.[13] Education programs may grow the utilization of MTM services by building caregiver awareness and assisting them with requesting or completing a CMR.

These grants could also support specialty pharmacy programs that train caregivers to administer injections and infusions at home, enabling pharmacies to direct staff to patients without caregivers. These grants would be beneficial to efforts conducted by health plans and specialty pharmacies to increase medication adherence, particularly for drugs with complicated administration.

**Sec. 202. Increasing Health Literacy to Promote Better Outcomes for Patients**

This section requires CMS to solicit feedback on ways to promote evidence-based, culturally competent health literacy strategies that improve patient outcomes.

[11] https://www.jmcp.org/doi/full/10.18553/jmcp.2019.25.6.688

[12] Medication Therapy Management in Chronically Ill Populations: Final Report

[13] Allen, A. and Hung, A. (2024). *Racial and ethnic disparities related to the Medicare Part D Medication Therapy Management Program*. Journal of Managed Care & Specialty Pharmacy, Vol. 30, No. 6. https://doi.org/10.18553/jmcp.2024.30.6.609.

*AMCP Response:*

**AMCP supports this provision.** Shortcomings in health literacy are associated with many negative patient outcomes, including nonadherence to prescriptions. As the Cures 2.0 Act acknowledges in Section 201, medication nonadherence is a serious health concern that can lead to preventable hospitalizations, illness, and even death. Nonadherence also imposes increased burdens and costs on our already-strained healthcare system. AMCP looks forward to being a resource to Congress during the legislative process and to CMS as it gathers information pursuant to this section.

**Sec. 203. Increasing Diversity in Clinical Trials**

This section proposes to require an updated report on demographic information included in FDA drug applications, commission a Government Accountability Office (GAO) report study on barriers to trial participation, conduct a public awareness campaign to encourage participation, and improve ClinicalTrials.gov for users.

*AMCP Response:*

**AMCP applauds Cures 2.0 for addressing this need and strongly supports this provision.** AMCP convened a stakeholder forum titled "Racial Health Disparities: A Closer Look at Benefit Design," which brought together more than 40 experts representing payers, pharmacy benefit managers, integrated delivery systems, health economists, patient advocates, academicians, biopharmaceutical manufacturers, and other key stakeholders within managed care. At the event, these stakeholders worked to identify potential structural issues in the current prescription drug formulary and benefit design processes and proposed viable solutions to reduce racial health disparities. One of the key principles that emerged from the discussion is a need to improve gaps in data by developing clinical trials to intentionally increase diversity in enrollment, trial design, and subgroup reporting.[14]

AMCP supports the clinical trial provisions included in the Food and Drug Omnibus Reform Act of 2022, including requiring sponsors of investigational drugs or devices to submit Diversity Action Plans to the FDA. AMCP awaits more information on how this program will be implemented and whether Congress needs to take additional steps to promote meaningful

[14] *AMCP partnership forum: Racial health disparities – a closer look at benefit design.* (2021). Journal of Managed Care & Specialty Pharmacy, Vol. 28, No. 1. https://doi.org/10.18553/jmcp.2021.21217.

engagement of underrepresented groups in clinical trials. The agency released draft guidance on Diversity Action Plans on June 27.[15]

**Sec. 303. Cell and Gene Therapies**

This section requires the Secretary of Health & Human Services (HHS) to submit a report to Congress on future challenges regarding cell and gene therapy, strategies to address those challenges, additional resources and authorities the FDA needs to implement those strategies, and the current state of cell and gene therapies regulation.

*AMCP Response:*

**AMCP supports this report and encourages Congress to go further in Cures 2.0 to address the future challenges presented by the continued growth of cell and gene therapies by including the *MVP Act* (S. 4204/H.R. 2666).**

Cell and gene therapies represent a significant opportunity for patients, offering potentially curative treatments for previously uncurable diseases. AMCP supports the creation of this report to clearly identify where opportunities exist to improve access to cell and gene therapies. One such area where we know improvements are needed is in Medicaid programs, which is why AMCP also supports including the *MVP Act* in the final Cures 2.0 package.

**Sec. 304. Increasing Use of Real-World Evidence**

This section requires HHS to outline approaches to maximize and expand the use of real-world evidence (RWE) and to establish a task force to develop recommendations for encouraging patients to engage in real-world data generation.

*AMCP Response:*

**AMCP supports this provision and the expanded use of real-world evidence.** RWE plays an important role in promoting patient safety, informing coverage determinations, and regulatory decision-making. RWE is particularly important in assessing safety for subgroups or subpopulations who were not studied during clinical trials, such as those with varied co-occurring chronic conditions. AMCP further supports Cures 2.0's inclusion of diverse and under-represented patient populations in the development of RWE, consistent with our support for increased diversity in clinical trials.

[15] https://www.fda.gov/news-events/press-announcements/fda-guidance-provides-new-details-diversity-action-plans-required-certain-clinical-studies.

**Sec. 305. Improving FDA-CMS Communication Regarding Transformative New Therapies**
This section would establish an automatic communication requirement between FDA and CMS for Breakthrough Therapy drugs.

*AMCP Response:*
**AMCP supports this provision to speed patient access to new therapies.** With the growing availability of specialty drugs, coverage decisions can be delayed by high costs. Improving communications and coordination between FDA and CMS will allow for earlier coverage determinations that benefit Medicaid and Medicare populations, particularly those patients who most need breakthrough treatments.

**Sec. 401. GAO Study and Report**
This section would require the GAO to publish a study of how to enhance Medicare coverage and payment of innovative health technologies.

*AMCP Response:*
**AMCP supports this requirement for the GAO to produce a study on actions that can be taken to enhance Medicare coverage and payment of innovative health technologies.** Innovative health technologies, such as digital therapeutics, can provide needed treatments for beneficiaries with conditions such as chronic disease and substance use disorder and can "reduce inefficiencies, improve access, increase quality, and make medicine more personalized for patients."[16]AMCP supports research on actions that can be taken to increase coverage and payment of these treatments.

**Sec. 404. Coverage and Payment for Breakthrough Devices Under the Medicare Program**
This provision would codify the Medicare Coverage of Innovative Technologies (MCIT) coverage and payment pathway at the Centers for Medicare and Medicaid Services (CMS). The MCIT rule was withdrawn by CMS in November 2021. An alternative rule, the Transitional Coverage for Emerging Technologies (TCET) rule, was proposed in June 2023 and has not been finalized. Unlike MCIT, TCET is limited only to those products that fit into an existing benefit category.

*AMCP Response:*
**AMCP supports the development of a pathway for faster coverage determinations and payment for innovative technologies and as such, we support the inclusion of this section in Cures 2.0.** AMCP supports improving beneficiary access to innovative technologies established by the MCIT and subsequent TCET pathway rules from CMS. However, we were disappointed that the Cures 2.0 Act makes no mention of digital therapeutics given the potential represented by this emerging area of technology. AMCP appreciates the challenges that digital

[16] https://www.jmcp.org/doi/pdf/10.18553/jmcp.2020.19418

therapeutics pose for the Medicare program, and in particular the Medicare requirement that for any item to be covered under the program, it must meet a statutory benefit category. Therefore, **we are encouraged by the inclusion of the definition of a "specified breakthrough device" as "a breakthrough device with respect to which no Medicare benefit category exists."**[17] Including this definition would allow for faster Medicare coverage of innovative technologies and for beneficiary access to a broader range of digital therapeutics.

While the "specified breakthrough device" classification is an important step for Medicare coverage of digital therapeutics, **Congress should alleviate any uncertainty and include a provision establishing a Medicare benefit category for digital therapeutics in Cures 2.0 by including the *Access to PDTs Act*.** Since digital therapeutics encompass a wide variety of devices, a designated benefit category in Medicare will ensure that beneficiaries have faster access to these treatment options and will facilitate an easier coverage pathway for device manufacturers.

**AMCP also supports the provision in this section that would allow for continued coverage of and payment for innovative devices after the transitional period through the National Coverage Determination process** if HHS determines that the device improves quality of care and patient outcomes, improves the delivery of care, or reduces spending. This would prevent disruptions in coverage for Medicare beneficiaries and continue uniform nationwide coverage of innovative devices.

**Sec. 405. Secretary of Health and Human Services Report on Coverage for Innovative Technologies**

This section requires a report from HHS on the viability of establishing alternative coverage pathways for innovative technologies.

*AMCP Response:*

As previously mentioned, AMCP supports improving Medicare beneficiary access to innovative health technologies. **We support this requirement for HHS to issue a report including information on digital treatment alternatives, a standardized process for determining coverage of innovative technologies, and payment systems.** HHS should look to the work already being done on these issues by organizations such as AMCP and the Digital Therapeutics Alliance as it undertakes this work. We support the inclusion of a requirement for HHS to issue a request for information in this section so that the Department can hear directly from stakeholders.

[17] https://www.congress.gov/bill/117th-congress/house-bill/6000/text#H3951765609204887B88AC9A7122B2602.

**Conclusion**

AMCP appreciates the opportunity to comment on the *Cures 2.0 Act Request for Information*. We are committed to being a valuable resource to Congress on improving access to prescription drugs at lower costs, reducing costs in the health care system, and improving access to pharmacy and telehealth services. If you have any questions regarding AMCP's comments or would like further information, please contact Adam Colborn, director of government affairs, at 703-684-2646 or acolborn@amcp.org.

Sincerely,

Susan A. Cantrell. RPh, CAE
Chief Executive Officer