Legislative Summary
21st Century Cures Act

Summary
On December 13, 2016, President Barack Obama signed into law the 21st Century Cures Act (Cures). The bill, developed and passed by Congress over a two-year period, attempts to stimulate additional drug development and discovery of new cures and treatments for diseases such as cancer. In addition, the new law calls for further investments in the National Institutes of Health (NIH) and the Food and Drug Administration (FDA) to stimulate innovative projects and advance scientific discovery with respect to disease treatment.

ASHP provided input on several sections of the new law, including measures on antibiotic resistance and limited pathways. Along with other stakeholders including United States Pharmacopeia (USP), ASHP advocated against a proposal in an earlier draft that would have replaced the requirement for biologic drug manufacturers to obtain a monograph from USP, instead requiring use of an FDA-provided monograph, thus nullifying the widely accepted standards that USP has had in place for decades. The proposed change was removed from the final version.

Funding
The 21st Century Cures Act provides $4.8 billion of funding over 10 years to NIH for programs such as the Precision Medicine Initiative, the Brain Research through Advancing Innovative Neurotechnologies (BRAIN) initiative, cancer research, and regenerative medicine using adult stem cells. Cures also provides $500 million to the FDA over 10 years to move drugs and medical devices to patients faster, while maintaining the same level of safety and effectiveness.

The new law includes $1 billion over two years for grants to states to supplement opioid abuse prevention and treatment activities, such as improving prescription drug monitoring programs, implementing prevention programs, training for healthcare providers, and expanding access to treatment programs. ASHP previously advocated that Congress make necessary funds available to alleviate this public health problem, and we are pleased to see this funding for efforts to combat opioid abuse.

Antimicrobial Resistance
The Cures Act includes efforts to improve antimicrobial resistance by requiring FDA and the Centers for Disease Control and Prevention (CDC) to gather and report data on human resistance to antimicrobial drugs, as well as requiring CDC to develop a mechanism for healthcare facilities to report antimicrobial data that will be made available to the public.

In addition to the reporting requirements, the measure also creates a limited pathway for preapproved antimicrobial drugs to be used on a limited population. Use of these preapproved drugs would only occur in life-threatening situations. ASHP advocated in support of this provision and asked for inclusion of a requirement that these products be labeled appropriately to indicate their use in a highly limited population.
Home Infusion
The 21st Century Cures Act also adjusts reimbursement for certain home-infusion drugs. The new payment amount for Part B drugs infused through durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) items is changed to the methodology used for most physician-administered drugs: average Sales Price (ASP) plus 6 percent. This change is based on findings from the HHS Office of the Inspector General, which determined that the current payment methodology — 95 percent of Average Wholesale Price (AWP) — currently overpays for some drugs while underpaying for others. The provision is effective January 1, 2017, and is estimated to save $600 million over 10 years.

This provision was added to the Cures package as a way to help offset the cost of the entire legislation. It appears that stakeholder input was not solicited for this provision.

A new single, all-inclusive payment system for home-infusion services will be established beginning in 2021 to reimburse home-infusion services providers for the professional services and monitoring services associated with home infusions (including nursing services), which currently are not separately paid by Medicare. The Act establishes a broad list of new requirements and standards for suppliers of home infusion.

Health Information Technology
The new law makes some changes to the health information technology (HIT) infrastructure. Specifically it creates the HIT Advisory Committee, which will replace the HIT Policy Committee. The newly formed committee will focus on areas such as infrastructure, privacy, patient access to health information, security, and demographic information. Additionally, the committee will recommend certification criteria for vendors as well as testing and standards specifications by the National Institute of Standards and Technology (NIST).

The Office of the National Coordinator (ONC) will periodically convene the advisory committee to identify priority uses of HIT and focus on priorities such as meaningful use, MACRA implementation, value-based purchasing, and other quality/value-based payment schematics. The 25-member committee will include patients/consumers representatives and appointees of the Secretary of Health and Human Services (HHS), the U.S. House of Representatives and Senate, and the Comptroller General. The committee is required to submit an annual report to Congress and the HHS Secretary. Overall, the committee must reflect providers, ancillary healthcare workers, consumers, health plans, technology developers, researchers, patients, and relevant federal agencies.

The Act also includes a requirement for the Government Accountability Office to review patient access to health information, including barriers to access, complications for healthcare providers, and methods patients use to request personal health information.

Telehealth
Cures requires CMS to look at certain patient populations such as dually eligible and those with chronic conditions who could benefit from telehealth services. CMS is also required to examine the types of
services that could be provided, review how activities of Centers for Medicare and Medicaid Innovation (CMMI) may fit in with telehealth, and look at barriers.

**Hospital Readmissions**
The new law also makes changes to the methodology used in calculating hospital readmission rates for reimbursement purposes. This new methodology will account for socioeconomic status among the factors that determine whether a readmission counts against the penalty-incurring threshold. Specifically, readmissions would account for the number of dual eligible patients

**MS-DRG Codes**
The new law will require CMS to move 10 surgical procedures from inpatient coding to outpatient Health Care Common Procedures Classification System (HCPCS) codes. The procedures to which this applies will be determined by HHS. This must be completed by January 1, 2018.

**Impact on Pharmacy**
It is important to note that, although ASHP provided input on earlier versions of the 21st Century Cures Act, the final version of the legislation was made available to the public only days before Congress voted to pass it. There was no opportunity to review and provide feedback on the impact of this legislation. In large part, ASHP supports many aspects of the law, including provisions aimed at funding for NIH and FDA, antibiotic resistance, and to support efforts to curb opioid abuse and addiction. Other sections, such as the change to the reimbursement rate for certain home-infusion services, are more concerning. With respect to other sections of the law, it may be some time before the true impact on pharmacy, if any, is known.