$1 billion opioids package passed with “Cures” bill

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The Senate today completed consideration of the “21st Century Cures Act,” approving the bill by a vote of 94 to 5. The House last week passed the bill 392 to 26. After several years of hearings, meetings and negotiations, and with bipartisan support from Congress and the White House, the $6.3 billion medical innovation package is intended to accelerate the discovery, development and delivery of new therapies, including $1 billion to help states address the opioid epidemic.

As with any legislative package of this size, there are provisions which have the support of physicians and provisions that raise some concerns. However, in the interest of advancing the many positive elements of the final bill, the AMA is in support of the final product.

One AMA-supported provision that would have clarified Sunshine Act reporting obligations for medical reprints and continuing medical education, for example, was struck during final negotiations.

Supported provisions

Some of the elements in the bill are supported by AMA policy. It includes $4.8 billion in funding for the National Institutes of Health (NIH) and additional funding for Vice President Biden’s Cancer Moonshot initiative. The Precision Medicine Initiative and the Brain Research through Advancing Innovative Neurotechnologies (BRAIN) programs also received funding in the wide-ranging package.

Importantly, $1 billion will be distributed to states over two years to assist in addressing the epidemic of opioid misuse and abuse through:

- Improving state prescription drug monitoring programs (PDMP)
- Implementing prevention activities and evaluating such activities to identify effective strategies to prevent opioid abuse
- Training for health professionals, such as best practices for prescribing opioids, pain management, recognizing potential cases of substance abuse, referral to treatment

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programs and overdose prevention
Supporting access to health care services, including those provided by federally certified opioid treatment programs or other health professionals to treat substance use disorders
Other public health-related activities, as the state determines appropriate, related to addressing the opioid abuse crisis within the state

Other provisions in the bill include:

- Funding for the U.S. Food and Drug Administration (FDA) to meet its various priorities and obligations
- Significant funding for many elements of the Helping Families in Mental Health Crisis Act, intended to make improvements to the nation’s mental health system
- More protections for human participants in clinical research and provisions to streamline and simplify Institutional Review Board (IRB) requirements
- Requiring that Medicare Advantage and Medicare Part D plans provide beneficiaries with an option to change plans during the first three months of the benefit year
- New authority for the U.S. Department of Health and Human Services (HHS) Office of the Inspector General to investigate and penalize acts of information blocking—the first financial penalties that can be directed at electronic health record (EHR) developers and vendors.

**Reporting burdens**

The AMA supports a provision excluding those who furnish most of their Medicare services at ambulatory surgical centers from penalties under the EHR Meaningful Use program and from the Merit-Based Incentive Payment System (MIPS) under the Quality Payment Program.

Addressing physician reporting burdens, the bill also allows physicians to delegate certain EHR documentation requirements to non-physician staff. Key interoperability problems were also tackled in the bill by establishing a directory of health professionals so that physicians can easily contact each other.

In a Dec. 3 radio address, President Obama voiced strong support for the bipartisan bill, saying, “I’ll sign it as soon as it reaches my desk.”