

Summary of Provisions in Cures Act:

PRO	CON
<p>\$4.8 billion over 10 years to NIH.</p>	<p>The increased funds only go to four projects, the Precision Medicine Initiative, the BRAIN Initiative, cancer research, and regenerative medicine using adult stem cells.</p>
<p>Provides \$500 million to the FDA over 10 years to implement new provisions.</p>	<p>Significant cuts to the Public Health and Prevention Fund is a major part of the budget offset.</p>
<p>Reauthorizes the NIH for FY 18-20</p>	<p>Specifies 5-year terms for institute Directors – allows for reappointment without limit.</p>
<p>Creates a “Next Generation of Researchers Initiative” in the Office of the Director to coordinate, develop, modify, and prioritize policies and programs to improve opportunities for new researchers.</p>	<p>Directors of institutes must review and make final decisions on funding awards.</p>
<p>Requires the Secretary of HHS and NIH Director to take action to reduce administrative burden for researchers, for example by evaluating financial reporting requirements and laboratory animal regulations and policies.</p>	<p>The HHS Secretary must submit a report to Congress on efforts to prevent and eliminate duplicative biomedical research that is “not necessary for scientific purposes.”</p>
<p>Exempts voluntary information collected during NIH research from paperwork reduction initiatives</p>	<p>Congress still needs to vote every year to make the funds above available as part of the appropriations process.</p>
<p>Allows expanded use of other transactions authority by institutes with the approval of the NIH Director and encourages the conduct and support of high-risk, high-reward research to address major challenges.</p>	<p>New review pathway for some drugs has the potential to miss important safety concerns with a particular medicine</p>
<p>Requires the Director of NIH to improve research related to minority populations.</p>	<p>Reduces the payment update that was included in the bipartisan Medicare and CHIP Reauthorization Act (MACRA) of 2015. Specifically, the update of 0.5 percent for fiscal year 2018, is changed to an update of 0.4588. (I think this is just Part A charges)</p>

<p>Requires the Director of NIH to update guidelines for the inclusion of women in clinical research to reflect the most current science.</p>	
<p>Requires that a working group be formed to develop recommendations towards a formal policy to enhance rigor and reproducibility of NIH-funded research. The working group shall consider analysis of sex as a biological variable.</p>	
<p>Establishes a Task Force on Research Specific to Pregnant and Lactating Women to provide guidance and advice with the goal of addressing gaps in knowledge and research regarding safe and effective therapies for pregnant and lactating women.</p>	
<p>Encourages NIMHD to include in its strategic plan ways to increase representation of underrepresented populations in clinical trials.</p>	
<p>Improves the ability of NIH and FDA scientists to attend scientific conferences.</p>	
<p>Speeds access to new drug therapies with a new review pathway</p>	
<p>Expedites interoperability among EHRs by developing or supporting a voluntary model framework and common agreement for the secure exchange of health information</p>	
<p>Exempts certain transfers of value from reporting requirements that health care providers have noted have a chilling effect on their engagement in CME (ie journal reprints) (I believe this provision was stripped out with the manager's amendment)</p>	
<p>Sets payment amounts for Part B drugs infused through durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) items using the methodology used for most physician-administered drugs: Average Sales Price (ASP) plus 6 percent. Applying the ASP+6 percent methodology to DMEPOS infused drugs would result in payment</p>	

amounts that reflect actual transaction prices. This change is based on findings from the HHS OIG which found that the current payment methodology – based on manufacturer sticker prices that were in effect in 2003 – currently over pays some drugs while underpaying for others