

H.R. 19, THE LOWER COSTS, MORE CURES ACT

Section by Section

STATS AT A GLANCE:

- 350 pages
- More than 40 bipartisan provisions that can go to the President's desk today
- Achieves the President's and Congress's shared goals of coming together to lower out-of-pocket health care costs for Americans

SECTION BY SECTION:

- **Title I- Medicare Parts B and D**
 - Subtitle A- Medicare Part B Provisions
 - *Section 101 – This provision provides for increased pricing transparency by expanding a Medicare online tool to allow beneficiaries to compare costs across three settings: hospital outpatient department, ambulatory surgical centers and the outpatient prospective payment system.*
 - *Section 102– This provision requires manufacturers of certain single-dose containers or single-use package drugs under Medicare Part B— excluding new drugs and drugs that require filtration— to provide refunds with respect to discarded amounts of such drugs.*
 - *Section 103 – This provision provides for variation in payment for certain drugs covered under Part B of the Medicare Program. The current system may have unintended consequences of encouraging manufacturers to price drugs higher to entice prescribing. This provision would encourage providers to provide lower cost drugs by applying variable percentages of ASP based on the relative drug cost, lowering beneficiaries' out of pocket spending.*
 - *Section 104 – This provision creates maximum add-on payments for certain drugs and biologicals (\$1,000 for most drugs and \$2,000 for certain immunotherapies), which reduces out-of-pocket costs for patients.*
 - *Section 105 – This provision requires a site-neutral payment for the administration of a Medicare Part B drug at the lower physician fee schedule rate rather than the rate paid to hospitals, lowering federal spending and beneficiary cost-sharing.*
 - Subtitle B- Drug Pricing Transparency
 - *Section 111 – This provision provides for drug pricing transparency, including reporting on excessive price hikes.*
 - *Section 112 – This provision provides for public disclosure of drug discounts.*
 - *Section 113 – This provision provides for a study of pharmaceutical supply chain intermediaries and merger activity.*
 - *Section 114 – This provision requires certain manufacturers to report drug pricing information with respect to drugs under the Medicare program*
 - *Section 115 – This provision makes prescription drug marketing sample information reported by manufacturers available to certain individuals and entities.*

- *Section 116 – This provision requires prescription drug plan sponsors to include real-time benefit information as part of such sponsor’s electronic prescription program under the Medicare program.*
 - *Section 117 – This provision is a sense of Congress regarding the need to expand commercially available drug pricing comparison platforms.*
 - *Section 118 – This provision provides for technical corrections to the implementation of the bipartisan 21st Century Cures Act, specifically related to interoperability.*
 - *Subtitle C- Medicare Part D Benefit Redesign*
 - *Section 121 – This provision provides for the biggest modernization of the Medicare Part D benefit since its passage— including a \$3,100 out-of-pocket cap, eliminating the donut hole, and adding a 10% manufacturer responsibility throughout the benefit which will lower federal spending and beneficiary cost-sharing.*
 - *Subtitle D- Other Medicare Part D Provisions*
 - *Section 131 – This provision applies to transitional coverage and retroactive Medicare Part D coverage for certain Low-Income Beneficiaries.*
 - *Section 132 – This provision allows for expanded Part D plan options, including incentives to provide a share of rebates at the point-of-sale.*
 - *Section 133 - This provision allows certain enrollees of prescription drug plans and MA-PD plans under the Medicare program to spread out cost-sharing.*
 - *Section 134 – This provision establishes a monthly \$50 post-deductible cap for insulin and insulin supplies for seniors, starting in 2022.*
 - *Section 135 – This provision addresses an out of pocket cliff currently in statute that if not addressed will increase out-of-pocket costs for seniors in 2020.*
 - *Subtitle E- MedPAC*
 - *Section 141 - This provision provides MedPAC and MACPAC access to certain drug information including certain rebate information.*
- **Title II- Medicaid**
 - *Section 201 - This provision sets a sunset on the limit on maximum rebate amounts for single source drugs and innovator multiple source drugs by including the language “before January 1, 2023”.*
 - *Section 202 - This section would amend the Social Security Act (SSA) Section 1927(d)(4) to enhance state Medicaid program requirements applicable to Patient & Therapeutic committees.*
 - *Section 203 - This provision would require GAO to investigate potential and existing state Medicaid program DUR board and P&T committee conflicts of interest.*
 - *Section 204 - This provision would amend SSA Section 1927(b)(3) to improve oversight of the information COD manufacturers agree to submit when they participate in the Medicaid drug rebate program.*
 - *Section 205 - This provision improves transparency and prevents the use of abusive spread pricing and related practices in Medicaid.*
 - *Section 206 - The HHS Secretary would be required to publish a report on Medicaid provider prescribing patterns for covered outpatient drugs for each state, and to the extent possible, for the five U.S. territories.*
 - *Section 207 - The provision would add an option for states under SSA Section 1927 to pay for certain covered outpatient drugs through risk-sharing value-based agreements beginning January 1, 2022.*
 - *Section 208- This provision would amend the Social Security Act (SSA) Section 1927(k)(3) to provide, at the option of a state, that the term “covered outpatient drug” may include any drug, biological product, or insulin as part of a bundled payment if it is provided on an outpatient*

basis as part of, or as incident to and in the same setting as, physicians' services or outpatient hospital services.

▪ **Title III- Food and Drug Administration**

- *Subtitle A- CREATES*
 - *Section 301 to 303 - These provisions allows for actions against bad actors who delay generics and biosimilars coming to market by withholding drug samples.*
- *Subtitle B- Pay-for-Delay*
 - *Section 311 to 315 - These provisions are aimed at agreements that prevent generics and biosimilars from coming to market.*
- *Subtitle C- BLOCKING Act*
 - *Section 321 - This provision is aimed at changing conditions of first generic exclusivity to spur access and competition.*
- *Subtitle D- Purple Book*
 - *Section 331 to 332 - These provisions require a public listing of the marketing or licensure status of biological products for the purpose of streamlining new product entry to the market.*
- *Subtitle E- Orange Book*
 - *Section 341 to 342 - These provisions require the submission of patent information for brand name drugs for the purpose of streamlining new product entry to the market.*
- *Subtitle F- Advancing Education on Biosimilars*
 - *Section 351 - This provision provides for increased education on biosimilars by providing certain educational materials and continuing education to physicians, crediting to MIPS.*
- *Subtitle G – Streamlining Transition of Biological Products*
 - *Section 361 – This provision allows certain products, like insulin, to continue under their current FDA drug approval pathway after March 23, 2020, and then– subsequent to approval– be deemed as a biologic, which will help them get to market sooner.*
- *Subtitle H – Over the Counter Monograph Safety, Innovation, and Reform*
 - *Section 370 to 382 – This provision provides new authorities to the FDA aimed at increasing the number of over-the-counter products available, which will lower costs for consumers.*
- *Subtitle I – Other Provisions*
 - *Section 391 – This provision prevents manufacturers from gaming the system by receiving additional exclusivity periods once they are deemed biologics.*
 - *Section 392 – This provision clarifies that in order to get new exclusivities, all orphan drugs must prove clinical superiority to a previous version of the drug already on the market.*
 - *Section 393 – This provision streamlines the approval process by providing clarity for biosimilar applicants that they can include information in their application showing the proposed conditions of use have been previously approved for the reference product.*
 - *Section 394 - This provision limits the potential for 'evergreening' by restricting manufacturers from obtaining new exclusivities on previously approved clinical entities.*

▪ **Title IV- Tax**

- *Section 401 – This provision makes permanent the 7.5% AGI threshold for purposes of the medical expense deduction.*
- *Section 402 – This provision provides a safe harbor for high deductible health plans without a deductible for insulin.*

- *Section 403 – This provision allows all tax-favored health accounts to be used to purchase over-the-counter medical products and adds feminine or menstrual care products to the list of qualified medical expenses for the purposes of these tax-favored health accounts.*

- **Title V- Miscellaneous**

- *Section 501 - This provision ensures biosimilars cannot be paid more than their reference product during the initial period.*
- *Section 502 – This provision requires a GAO study and report on the average sales price (ASP).*
- *Section 503 – This provision requires prescription drug plans and MA-PD plans to report potential fraud, waste, and abuse to the secretary of HHS.*
- *Section 504 – This provision establishes pharmacy quality measures under Medicare Part D.*
- *Section 505 – This provision improves coordination between the FDA and CMS by requiring a public meeting and report.*
- *Section 506 – This provision deals with patient consultation in Medicare national and local coverage determinations in order to mitigate barriers to inclusion of such perspectives.*
- *Section 507 – This provision requires a MedPAC report on shifting coverage of certain Medicare Part B drugs to Medicare Part D.*
- *Section 508 – This provision codifies recent regulations from the U.S. Department of Health and Human Services to require pharmaceutical companies to list prices of their prescription drugs in direct-to-consumer advertisements.*
- *Section 509 – This provision creates a Chief Pharmaceutical Negotiator at the Office of the United States Trade Representative.*
- *Section 510 – This provision waives Medicare coinsurance for colorectal cancer screening tests.*