The Lower Costs, More Cures Act of 2019

Legislation designed to deliver lower drug costs for Americans while encouraging the development of new treatments and cures.

TITLE I: MEDICARE	
SUBTITLE A: MEDICARE PART B	
Section 101. Improving Medicare site-of-service transparency.	Updates Medicare's Procedure Price Lookup transparency tool to allow beneficiaries to compare costs across settings, including hospital outpatient departments, ambulatory surgical centers, and physician offices, better informing Medicare enrollees about their costs of care.
Section 102. Requiring manufacturers of certain single-dose container or single-use package drugs payable under Medicare Part B to provide refunds with respect to discarded amounts of such drugs.	Requires drug and biological manufacturers to refund the amount of payment made to providers for certain unused products. Refunds would be deposited into the Medicare Supplementary Medical Insurance Trust Fund.
Section 103. Providing for variation in payment for certain drugs covered under the Medicare Part B program.	Requires the Secretary to determine the payment of a Part B drug based on the percentile rank of the allowable cost of a drug or biological. The corresponding percentage of the average sales price (ASP) reimbursement rate would be as follows: • At least equal to the 85th percentile is 104% • At least equal to the 70th percentile is 106% • At least equal to the 50th percentile is 108% • Less than the 50th percentile is 110%
Section 104. Establishing a maximum add-on payment for drugs and biologicals.	Provides for the creation of a maximum add-on payment under Medicare Part B to better align incentives for physicians administering these medications. The payments would be as follows: • Up to $1,000 for most drugs and biologicals; and • Up to $2,000 for certain immunotherapies. The payments would be updated annually according to inflation by CPI-U.
Section 105. Treatment of drug administration services furnished by certain excepted off-campus outpatient departments of a provider.	Establishes a site-neutral payment for the services associated with administering a Medicare Part B drug. The reimbursement rate would be tied to the physician fee schedule regardless of the setting in which the drug was administered.

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Section 106. Payment for biosimilar biological products during initial period.	Establishes a payment rate for biosimilars that is the lesser of: • The biosimilar's wholesale acquisition cost plus three percent; or • The amount determined for the biological reference product.
Section 107. Education on biological products.	Permits Merit-based Incentive Payment Systems (MIPS)-eligible professionals, once during their lifetimes, to count completion of a clinical medical education program on biological and biosimilar products towards their score under the performance category.
Section 108. GAO study and report on average sales price.	Provides for a GAO study and report on payment for Medicare Part B drugs that includes an analysis of the following: • The extent to which a drug is paid for under Part B or by private payors in the commercial market • Any change in Medicare spending or beneficiary cost-sharing if ASP was based solely on payments made by private payors in the commercial market • Barriers to manufacturers providing price concessions • The extent to which manufacturers provide rebates, discounts or other price concessions to private payors for a drug, which the manufacturer includes in its ASP calculation for formulary placement, or utilization management considerations.
SUBTITLE B: MEDICARE PART D	

Section 111. Medicare Part D benefit redesign.	Updates the structure of the Medicare Part D program to modernize the benefit and realign incentives. The new standard benefit design would be as follows:
	• Deductible: The beneficiary would be responsible for 100 percent of costs ($435 in CY 2020)
	• Initial Coverage Phase:
	  ○ Beneficiary would be responsible for 15 percent
	  ○ Manufacturer would be responsible for 10 percent
	  ○ Plan would be responsible for 75 percent
	• Out-of-pocket cap: $3,100
	• Catastrophic Coverage Phase:

	○ Beneficiary would not have cost-sharing liability ○ Manufacturer would be responsible for 10 percent ○ Plan would be responsible for 70 percent ○ Medicare would be responsible for 20 percent
Section 112. Transitional coverage and retroactive Medicare Part D coverage for certain low-income beneficiaries.	Permanently authorizes the Limited Income Newly Eligible Transition (LI NET) program, which ensures immediate, temporary prescription drug coverage for beneficiaries who qualify for low-income subsidies but are not yet covered by a Part D plan.
Section 113. Allowing the offering of additional prescription drug plans under Medicare Part D.	Allows prescription drug plan sponsors to offer, at minimum, up to four Part D plans per region. Further, plan sponsors could offer two additional plans per region if one of those plans passes at least 25 percent of aggregate price concessions to the beneficiary at the point-of-sale.
Section 114. Allowing certain enrollees of prescription drug plans and Medicare Advantage-Prescription Drug plans to spread out cost-sharing.	Requires the Secretary, through rulemaking, to establish a process by which beneficiaries who reach a specified significant percentage of their annual out-of-pocket maximum within a 30-day period to pay their annual out-of-pocket costs in monthly installments. In determining the definition of significant percentage, the Secretary cannot specify an amount less than 30 percent or greater than 100 percent of the annual out-of-pocket maximum.
Section 115. Establishing a monthly cap on beneficiary incurred costs for insulin products and supplies under a prescription drug plan or Medicare Advantage-Prescription Drug plan.	Establishes a monthly out-of-pocket maximum of $50 for insulin and insulin medical supplies after the deductible is met and before the enrollee's out-of-pocket cap is reached.
Section 116. Growth rate of Medicare Part D out-of-pocket cost threshold.	Prevents an increase in beneficiary out-of-pocket costs required to reach Part D's catastrophic phase through 2021.
Section 117. Requiring prescription drug plan sponsors to include real-time benefit information as part of such sponsor's electronic prescription program under the Medicare program.	Requires Medicare Part D plan sponsors to implement real-time benefit tools that are capable of integrating with a provider's electronic prescribing or health record system. The benefit tool would include the following: • A list of clinically-appropriate alternatives to a drug included on the formulary; • Cost-sharing information for a drug and alternatives; and

	• Information relating to whether a drug is included on the formulary and whether there are any prior authorization or other utilization management requirements.
Section 118. Requiring prescription drug plans and Medicare Advantage-Prescription Drug plans to report potential fraud, waste, and abuse to the Secretary.	Requires a prescription drug plan sponsor to report to the Secretary the following: • Any substantiated or suspicious activities with respect to the program as it relates to waste, fraud, and abuse; and • any steps made by the plan sponsor to take corrective action after identifying such activities.
Section 119. Establishment of pharmacy quality measures under Medicare Part D.	Requires prescription drug plan sponsors to only use quality measures established or adopted by the Secretary. The measures must be from a consensus, evidenced-based organization and focus on patient health outcomes.
TITLE II: TRANSPARENCY	
Section 201. Reporting on explanation for drug price increases.	For drugs with a wholesale acquisition cost (WAC) exceeding $100, requires the publication of certain information regarding any price increase equal to or exceeding 10 percent in a single calendar year or 25 percent or more in three consecutive calendar years. The information must be displayed in a manner that prevents disclosure of trade secrets and confidential commercial information.
Section 202. Requiring public disclosure of drug discounts.	Increases the transparency of certain health care payments by requiring the publication of certain information with respect to services provided by a health benefits plan or pharmacy benefit manager (PBM) for a contract year including: • Aggregate price concessions including discounts and rebates • The aggregate difference between the amount the health benefit plan pays the PBM and the amount the PBM pays pharmacies The information must be displayed in a manner that prevents the disclosure of certain proprietary data.

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Section 203. Requiring certain manufacturers to report drug pricing information with respect to drugs under the Medicare program.	Improves reporting of average sales price data for Part B drugs to incentivize broader use of ASP over WAC.
Section 204. Making prescription drug marketing sample information reported by manufacturers available to certain individuals and entities.	Requires the Secretary to maintain a list of information related to the distribution of samples of certain drugs, and share related data at the request of health oversight agencies, MedPAC, MACPAC, and certain researchers and payors.
Section 205. Providing the Medicare Payment Advisory Commission (MedPAC) and the Medicaid and CHIP Payment and Access Commission (MACPAC) with access to certain drug price and payment information.	Allows the Secretary to share Medicare Part D and Medicaid drug price and rebate data with the executive directors of MedPAC and MACPAC for the purposes of monitoring, making recommendations, and analysis of the programs. MedPAC and MACPAC are prohibited from disclosing information about specific amounts or the identity of the source of any rebates, price concessions, or information submitted as part of an insurer's annual bid.
Section 206. Sense of Congress regarding the need to expand commercially available drug pricing comparison platforms.	Expresses congressional support for drug pricing comparison platforms that can help patients find the lowest price for their drugs.
TITLE III: TAXES	
Section 301. Permanent extension of reduction in medical expense deduction floor.	Makes permanent the 7.5 percent adjusted gross income (AGI) threshold for the purposes of the medical expense deduction, ensuring taxpayers who itemize may claim this deduction once they spend 7.5 percent of their income on qualified health expenses.
Section 302. Safe harbor for high deductible health plans without a deductible for insulin.	Allows a high deductible health plan to maintain its designation if the plan offers coverage for insulin or any device for the delivery of insulin before the deductible is met.
Section 303. Inclusion of certain over-the-counter medical products as qualified medical expenses.	Adds over-the-counter drugs and feminine care products to the list of qualified medical expenses for tax-favored health savings accounts including Health Savings Accounts (HSAs), Archer Medical Savings Accounts (MSAs), Flexible Spending Accounts (FSAs), and Health Reimbursement Arrangements (HRAs).
TITLE IV: ADDITIONAL PROVISIONS TO LOWER DRUG COSTS	

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Section 401. Improving coordination between the Food and Drug Administration (FDA) and the Centers for Medicare and Medicaid Services (CMS).	Requires the Secretary to issue a report on Medicare processes with respect to the coding, coverage, and payment of novel medical products, including making recommendations on ways to incorporate patient experience data, decrease the length of time to make national and local coverage determinations under Medicare, streamline the Medicare coverage process, and identify ways to incorporate into Medicare novel payment designs used by commercial insurers. Requires the Secretary to convene a public meeting on improving FDA and CMS coordination and update and finalize guidance on national coverage determinations following that meeting.
Section 402. Patient consultation in Medicare national and local coverage determinations in order to mitigate barriers to inclusion of such perspectives.	Allows the Secretary to consult with patients and organizations representing patients in making national and local coverage determinations.
Section 403. MedPAC report on shifting coverage of certain Medicare Part B drugs to Medicare Part D.	Provides for a MedPAC study on shifting coverage of certain drugs and biologicals from Medicare Part B to Medicare Part D. The analysis would include the following: • The differences in program structures and payment methods for drugs under Parts B and D, including the potential effects on beneficiary cost-sharing, utilization management techniques, and the feasibility and policy implications of shifting coverage.
Section 404. Requirement that direct-to-consumer advertisements for prescription drugs and biological products include truthful and non-misleading pricing information.	Requires the Secretary to establish direct-to-consumer advertising parameters including: • The forms of advertising; • The manner of disclosure; • The price point listing; and • The price information for disclosure.
Section 405. Chief Pharmaceutical Negotiator at the Office of the United States Trade Representative (USTR).	Establishes the role of Chief Pharmaceutical Negotiator within the USTR to ensure equitable treatment of United States patients in trade deals.