

S. 2164, the Lower Costs, More Cures Act of 2021

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

TITLE I: MEDICARE AND MEDICAID PROVISIONS	
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: <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> • Up to \$1,000 for most drugs and biologicals; and • Up to \$2,000 for certain immunotherapies. <p>The payments would be set for an initial period and then updated annually according to inflation by CPI-U.</p>
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.
Section 106. Payment for biosimilar biological products during initial period.	Establishes a payment rate for biosimilars that is the lesser of: <ul style="list-style-type: none"> • The biosimilar’s wholesale acquisition cost plus three percent; or • The amount determined for the biological reference product.

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<p>Section 107. Credit under the Medicare Merit-Based Incentive Payment System for completion of a clinical medical education program on biosimilar biological products.</p>	<p>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.</p>
<p>Section 108. GAO study and report on average sales price.</p>	<p>Provides for a GAO study and report on payment for Medicare Part B drugs that includes an analysis of the following:</p> <ul style="list-style-type: none"> • 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.
<p>SUBTITLE B: MEDICARE PART D</p>	
<p>Section 111. Medicare Part D benefit redesign.</p>	<p>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:</p> <ul style="list-style-type: none"> • Deductible: The beneficiary would be responsible for 100 percent of costs (\$445 in CY 2021) • Initial Coverage Phase: <ul style="list-style-type: none"> ○ 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: <ul style="list-style-type: none"> ○ Beneficiary would not have cost-sharing liability ○ Manufacturer would be responsible for 10 percent ○ Plan would be responsible for 70 percent

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	<ul style="list-style-type: none"> ○ Medicare would be responsible for 20 percent
Section 112. 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 113. 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 114. Continuation of Part D Senior Savings Model.	Requires the Secretary to make permanent the Center for Medicare and Medicaid Innovation model that enables Part D enrollees taking insulin to limit their out-of-pocket costs to \$35 per month. This would continue the current program that has robust voluntary participation from insulin manufacturers and prescription drug plans and has saved enrollees \$450 in annual out-of-pocket costs.
Section 115. 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: <ul style="list-style-type: none"> • 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 116. 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.
SUBTITLE C: MEDICAID	
Section 121. Price reporting clarifications for gene therapy outcomes-based agreements.	Updates the Medicaid Drug Rebate Program to allow states to participate in outcomes-based agreements in Medicaid for single course transformative therapies. The changes would incentivize innovative state approaches by allowing a variety of outcomes-based agreements and updating the definition of average manufacturing price and Medicaid best price.

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<p>Section 122. Anti-kickback statute and physician self-referral safe harbors.</p>	<p>Excludes outcomes-based agreements (as defined in Section 121) from violating the anti-kickback statute and the physician self-referral prohibition (commonly referred to as the “Stark law”) to avoid unnecessary barriers to such agreements. For instance, the changes would ensure that nonpayment by a state to a manufacturer for a single course transformative therapy under an agreement is not an anti-kickback violation.</p>
<p>Section 123. GAO study and report on use of outcomes-based agreements.</p>	<p>Requires a Government Accountability Office study and report on whether outcomes-based agreements:</p> <ul style="list-style-type: none"> • Change patient access to gene therapies for rare diseases; • Lower health system costs; • Lower Federal health program costs; and • Reduce health disparities.
<p>TITLE II: TRANSPARENCY</p>	
<p>Section 201. Reporting on explanation for drug price increases.</p>	<p>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.</p>
<p>Section 202. Requiring public disclosure of drug discounts.</p>	<p>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:</p> <ul style="list-style-type: none"> • 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 <p>The information must be displayed in a manner that prevents the disclosure of certain proprietary data.</p>
<p>Section 203. Making prescription drug marketing sample information reported by manufacturers available to certain individuals and entities.</p>	<p>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.</p>
<p>Section 204. Sense of Congress regarding the need to expand commercially available drug pricing comparison platforms.</p>	<p>Expresses congressional support for drug pricing comparison platforms that can help patients find the lowest price for their drugs.</p>

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TITLE III: TAX BENEFIT	
Section 301. Inclusion of insulin and other treatments for chronic conditions as preventive care.	Allows a high deductible health plan to cover insulin and insulin delivery devices and supplies (and other preventive services) before the deductible is met.
TITLE IV: ADDITIONAL PROVISIONS TO LOWER DRUG COSTS	
Section 401. Improving coordination between the Food and Drug Administration (FDA) and the Centers for Medicare and Medicaid Services (CMS).	<p>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:</p> <ul style="list-style-type: none"> • 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. <p>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.</p>
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.	<p>Provides for a MedPAC study and report on shifting coverage of certain drugs and biologicals from Medicare Part B to Medicare Part D. The analysis would include:</p> <ul style="list-style-type: none"> • 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. Authority to require that direct-to-consumer advertisements for prescription drugs and biological products include truthful and non-misleading pricing information.	<p>Allows the Secretary to require that direct-to-consumer advertising include a link to a website with pricing information. The Secretary would establish parameters relating to any such requirement that include:</p> <ul style="list-style-type: none"> • The forms of advertising; • The manner of disclosure; • The price point listing; and • The price information for disclosure.

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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.