

# ACCELERATED APPROVAL DRUGS DO NOT DRIVE MEDICAID SPENDING

PARTNERSHIP TO FIGHT CHRONIC DISEASE  
A VISION FOR A HEALTHIER AMERICA

**The Food and Drug Administration’s accelerated approval pathway is an important way to provide faster access to safe and effective therapies for patients with serious diseases where limited or no other treatments exist.**

Since 1992, **more than 270 therapies have been approved via the accelerated approval pathway<sup>1</sup>**. Nearly 80% of accelerated approval drugs<sup>2</sup> approved prior to 2020 have been converted to traditional approval, and of the remaining, confirmatory studies are underway. These drugs address chronic, life-threatening diseases, such as HIV/AIDS, many cancers, sickle cell disease, and rare diseases.

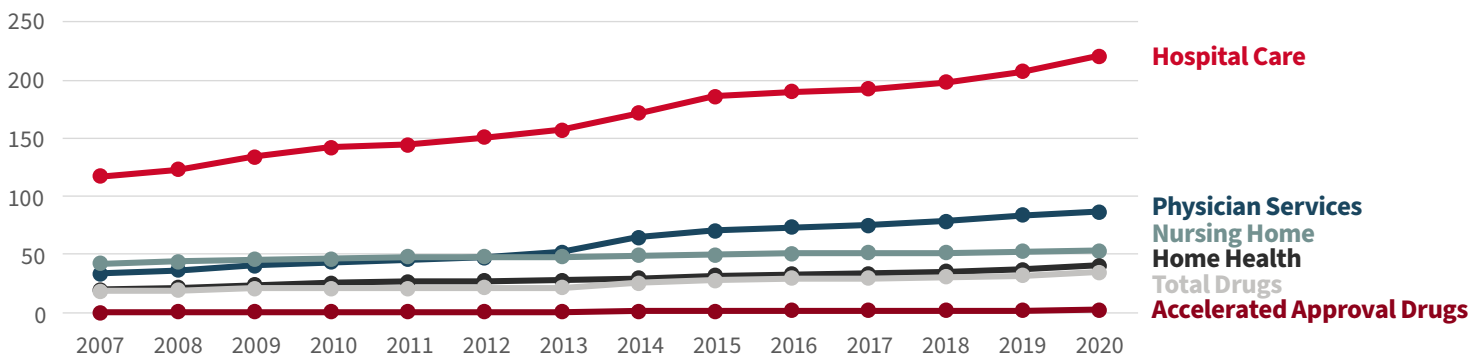
Under the pathway, FDA may approve a drug that demonstrates safety and efficacy in clinical trials using a surrogate or an intermediate clinical endpoint that is reasonably likely to predict clinical benefit.

Misunderstanding and misperceptions about the pathway and its impact on Medicaid spending have contributed to several recent misguided proposals. An analysis of publicly available data on Medicaid spending by Kenneth Thorpe, Chair of PFCD and of the Department of Health Policy & Management for the Rollins School of Public Health at Emory University, disputes concerns that accelerated approval drugs are driving Medicaid spending<sup>3</sup>.



## ACCELERATED APPROVAL DRUGS HAVE REMAINED A MINIMAL CONTRIBUTOR TO SPENDING GROWTH OVER TIME

**Distribution of Medicaid Spending by Source, 2007-2020**



**PROPOSALS TO RESTRICT ACCESS TO LIFE-SAVING TREATMENTS ARE NOT SUPPORTED BY THE DATA.**

Medicaid provides necessary health coverage to more than **77 million Americans, half of whom are children and 60 percent are racial or ethnic minorities**. To date, three states – Massachusetts (2017), Tennessee (2019) and Oregon (2022) – have sought waivers from the Centers for Medicare and Medicaid Services (CMS) to exclude coverage for accelerated approval drugs, citing budget impact concerns, but without supporting data.

1. <https://www.fda.gov/media/151146/download>  
 2. <https://www.youtube.com/watch?v=FcScXVVBVdw&list=PLDScWcpkQ5CyLJgOqkp2088IrV2FHRdk&index=8>  
 3. <https://bit.ly/pfcd-accelerated-approval-in-medicaid>

**IN STATES  
REQUESTING  
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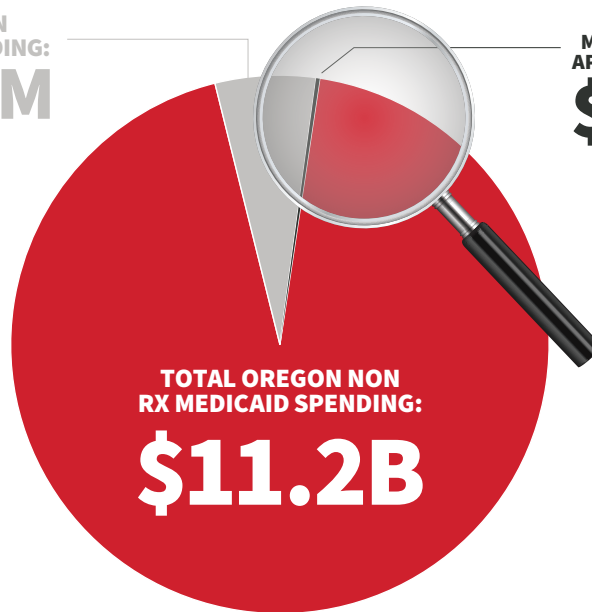
Spending data for Mass. (0.13%) and Tenn. (0.33%) confirm the minimal impact on total Medicaid spending in those states.

**Oregon Medicaid Spending on Accelerated Approval Drugs Relative to Overall Program Spending (2020)**

TOTAL 2020 OREGON  
MEDICAID RX SPENDING:  
**\$721.5M**

TOTAL 2020 OREGON  
MEDICAID ACCELERATED  
APPROVAL RX SPENDING:  
**\$12.5M**

**0.11%**  
OF TOTAL  
OREGON  
MEDICAID  
SPENDING

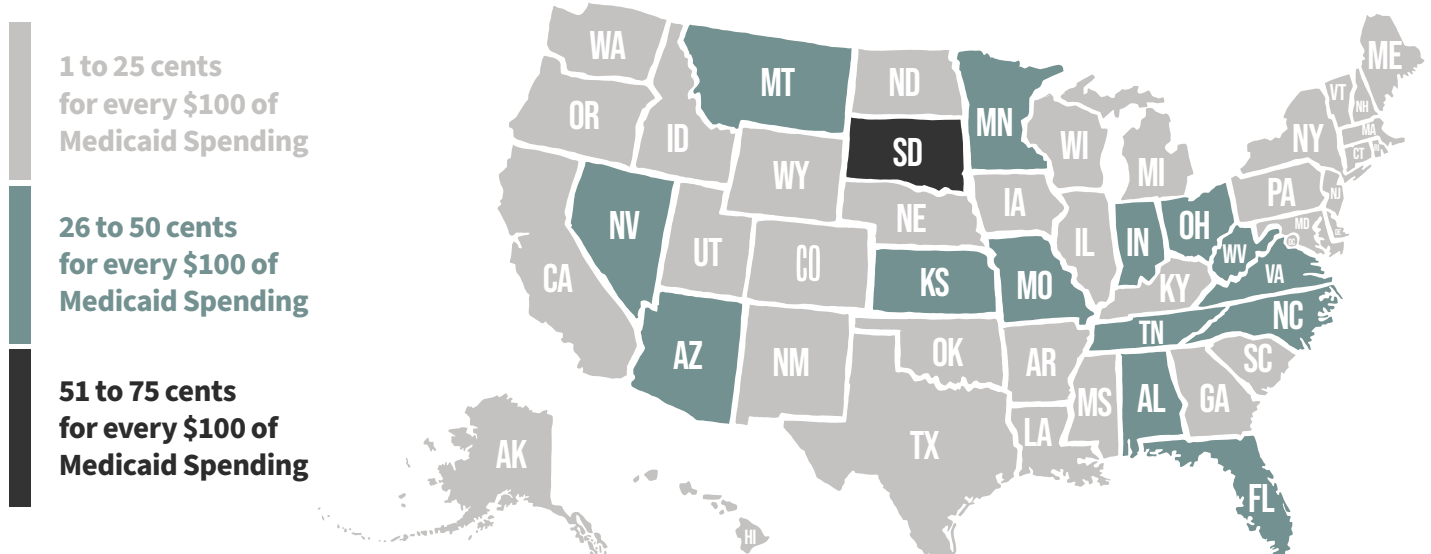


**Sources:** Form CMS-64 Reports, Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program - <https://www.macpac.gov/publication/medicaid-spending-by-state-category-and-source-of-funds/> State Drug Utilization Data - <https://www.medicaid.gov/medicaid/prescription-drugs/state-drug-utilization-data/index.html>

**COMPROMISING THE LIVES OF CHRONICALLY ILL MEDICAID PATIENTS BY DENYING ACCESS TO FDA-APPROVED DRUGS SETS THE WRONG PRECEDENT.**

**ACCELERATED APPROVAL DRUGS ACCOUNT FOR WELL UNDER \$1 FOR EVERY \$100 SPENT IN MEDICAID IN ALL STATES.**

2020 Pre-Rebate Spending on Accelerated Approval Drugs



States looking to reduce costs will not find savings by restricting access to accelerated approval therapies, as confirmed by the Thorpe analysis. State by state cost data suggests that similar to the national data findings, hospital, physician and nursing home care are the true cost drivers, and ultimately the areas to assess more closely when exploring opportunities for savings.