

**NATIONAL COALITION FOR CANCER SURVIVORSHIP**  
**Cancer Policy Roundtable**  
**March 28, 2024**

## **Cancer Patients are Getting Younger – Implications for Research, Treatment, and Survivorship Care**

### ***Cancer Statistics, 2024***

On January 17, 2024, the American Cancer Society (ACS) released its annual report, *Cancer Statistics, 2024*. The report noted that cancer mortality is still declining but also noted the increased incidence of certain cancers in young adults.

See below the beginning of the ACS announcement of the report (and the full announcement online: [https://pressroom.cancer.org/acs-cff-2024#:~:text=Cancer%20patients%20are%20getting%20younger,19%25%20for%20ages%2050%2D64](https://pressroom.cancer.org/acs-cff-2024#:~:text=Cancer%20patients%20are%20getting%20younger,19%25%20for%20ages%2050%2D64).)).

### **Cancer Mortality Still Declining, but Progress Threatened by Increasing Incidence as Projected New Cancer Cases Top Two Million for 2024**

**Jan 17, 2024**

**The annual American Cancer Society report also shows colorectal cancer is now the leading cause of cancer death in men and the second in women under 50 years old**

**ATLANTA, January 17, 2024** — The [American Cancer Society](#) (ACS) today released *Cancer Statistics, 2024*, the organization’s annual report on cancer facts and trends. The new data show overall cancer mortality has continued to decline, resulting in over 4 million fewer deaths in the United States since 1991. However, this progress is jeopardized by increasing incidence for 6 of the top 10 cancers as the projected number of new diagnoses now tops 2 million (2,001,140) for the first time. These important findings are published today in [CA: A Cancer Journal for Clinicians](#), alongside its consumer-friendly companion, *Cancer Facts & Figures 2024*, available on [cancer.org](#).

“We’re encouraged by the steady drop in cancer mortality as a result of less smoking, earlier detection for some cancers, and improved treatment,” said [Rebecca Siegel](#), senior scientific director, surveillance research at the American Cancer Society and lead author of the report. “But as a nation, we’ve dropped the ball on cancer prevention as incidence continues to increase for many common cancers – like breast, prostate, and endometrial, as well as colorectal and cervical cancers in some young adults.”

For the report, ACS researchers compiled the most recent data on population-based cancer occurrence and outcomes using incidence data collected by central cancer registries (through 2020) and mortality data collected by the National Center for Health Statistics (through 2021).

Rising colorectal cancer incidence has rapidly shifted mortality patterns in adults under 50 years of age; colorectal cancer has moved up from being the fourth leading cause of cancer death in both younger men and women two decades ago to first in men and second in women. Breast cancer leads in women under 50 with 2,251 deaths in 2021.

“The continuous sharp increase in colorectal cancer in younger Americans is alarming,” said [Dr. Ahmedin Jemal](#), senior vice president, surveillance and health equity science at the American Cancer Society and senior author of the study. “We need to halt and reverse this trend by increasing uptake of screening, including awareness of non-invasive stool tests with follow-up care, in people 45-49 years. Up to one-third of people diagnosed before 50 have a family history or genetic predisposition and should begin screening before age 45 years. We also need to increase investment to elucidate the underlying reasons for the rising incidence to uncover additional preventive measures.”

“The 2024 ACS cancer report underscores the importance of cancer prevention, and illuminates priority areas to address cancers whose incidence and/or mortality rates are inexplicably rising,” said [Dr. Karen E. Knudsen](#), chief executive officer at the American Cancer Society. “These observations highlight the critical need to invest in equitable application of proven cancer control interventions, and in discovery for new therapies -- especially for advanced-stage cancers. Both endeavors will be essential to accelerate progress against the 200 diseases we call cancer, and to save lives.”

Cancer Statistics, 2024 is available open access:

<https://acsjournals.onlinelibrary.wiley.com/doi/full/10.3322/caac.21820>.

### ***Strategies to Address Early-Onset Cancers***

A March 4, 2024, article in Yale Medicine addressed the increased incidence of cancer in young adults as well as options for detection and treatment of early-onset cancers. The article can be read online:

<https://www.yalemedicine.org/news/early-onset-cancer-in-younger-people-on-the-rise>

### ***Nature Magazine News Feature on Early-onset Cancer***

Read the beginning of the Heidi Ledford news feature on early-onset cancer and finish the article online: <https://www.nature.com/articles/d41586-024-00720-6>.

### **Why are so many young people getting cancer? What the data say Clues to a modern mystery could be lurking in information collected generations ago.**

Of the many young people whom Cathy Eng has treated for cancer, the person who stood out the most was a young woman with a 65-year-old's disease. The 16-year-old had flown from China to Texas to receive treatment for a gastrointestinal cancer that typically occurs in older adults. Her parents had sold their house to fund her care, but it was already too late. “She had such advanced disease, there was not

much that I could do,” says Eng, now an oncologist at Vanderbilt University Medical Center in Nashville, Tennessee.

Eng specializes in adult cancers. And although the teenager, who she saw about a decade ago, was Eng’s youngest patient, she was hardly the only one to seem too young and healthy for the kind of cancer that she had.

Thousands of miles away, in Mumbai, India, surgeon George Barreto had been noticing the same thing. The observations quickly became personal, he says. Friends and family members were also developing [improbable forms of cancer](#). “And then I made a mistake people should never do,” says Barreto, now at Flinders University in Adelaide, Australia. “I promised them I would get to the bottom of this.”

It took years to make headway on that promise, as oncologists such as Barreto and Eng gathered hard data. Statistics from around the world are now clear: the rates of more than a dozen cancers are increasing among adults under the age of 50. This rise [varies from country to country and cancer to cancer](#), but models based on global data predict that the number of early-onset cancer cases will increase by around 30% between 2019 and 2030<sup>1</sup>. In the United States, colorectal cancer — which typically strikes men in their mid-60s or older — has become the leading cause of cancer death among men under 50<sup>2</sup>. In young women, it has become the second leading cause of cancer death.

As calls mount for better screening, [awareness and treatments](#), investigators are scrambling to explain why rates are increasing. The most likely contributors — such as rising rates of obesity and early-cancer screening — do not fully account for the increase. Some are [searching for answers in the gut microbiome](#) or in the genomes of tumours themselves. But many think that the answers are still buried in studies that have tracked the lives and health of children born half a century ago. “If it had been a single smoking gun, our studies would have at least pointed to one factor,” says Sonia Kupfer, a gastroenterologist at the University of Chicago in Illinois. “But it doesn’t seem to be that — it seems to be a combination of many different factors.”

Read the rest of the Nature article online: <https://www.nature.com/articles/d41586-024-00720-6>

## Prescription Drug Affordability Boards

Ed Silverman of STAT News is not the only health reporter covering prescription drug affordability boards, but he is one of the best. See below a Silverman article from October 11, 2023, followed by an article from March 21, 2024. Together, the two Silverman pieces provide a good overview of the policy and politics of these boards and hint at their future.

### **Medicare may plan to negotiate drug prices, but some states are taking their own steps to lower costs**

October 11, 2023

Anticipation may be high that Medicare can wring lower prices out of drugmakers, but a handful of states are moving aggressively to slash costs for their residents, a clear sign the battle over affordable medicines in the U.S. is only going to escalate further.

These efforts involve Prescription Drug Affordability Boards, which are designed to function like a rate-setting authority. How so? Most boards seek to set upper payment limits, or ceilings, used for determining prices that are paid for medicines. And in some states, the plan is to set prices paid not just by state and local governments, but also by commercial health plans operating there.

“We know drug costs are too high because our patients skip doses or cut them in half,” said Rob Davidson, an emergency room doctor who is also executive director of the Committee to Protect Health Care, a national organization that lobbied to pass legislation to create a state board in Michigan. “So we should be excited about any move that could decrease costs.”

The concept is not new. It was, in fact, floated several years ago and gradually explored by lawmakers in several states that chafed at the lack of progress in Washington to address rising prescription drug costs. Since then, seven states created such boards, but in recent months, there has been a flurry of activity reflecting what supporters say is an increasingly pressing need to lower prescription drug costs.

Take Maryland. The state made headlines four years ago by creating the first board in the U.S., but is not expected to compile its first list of drugs for cost reviews until January. The board hopes to set upper payment limits on prices to be paid, but only by state and local government agencies. So consumer advocates are now pushing to expand its mandate to include residents covered by commercial insurers.

In May, Minnesota became the [latest state to establish](#) its own board and is expected to name its members by January. Meanwhile, the Michigan Senate recently [passed a bill](#) to create a board, which would make it the eighth state to take this step. The state House must still vote on the idea, although it is widely expected to pass and then become law, since Gov. Gretchen Whitmer has championed the idea.

Colorado has triggered particular attention. The board there can set payment limits that will apply to most residents, including those whose insurance is covered by a government agency or a commercial health plan. And in August, the board gained notice by choosing [the first five drugs](#) for cost reviews, including a pricey cystic fibrosis treatment, triggering debate about the effect on access to rare disease medicines.

The boards have somewhat different rules and criteria guiding their actions, but one thing they have in common is a concern that efforts by the federal government to lower drug costs will fall short. State lawmakers and officials praise the Inflation Reduction Act, the federal law that allows Medicare to negotiate drug prices. But they believe it does not go far enough, so there is still a need for the boards.

“The law is wonderful. It’s long overdue and will make people’s lives appreciably better, but it’s not the whole solution to the problem,” said Zack Stephenson, a Minnesota lawmaker who sponsored the bill

that created a state board. “It will only cover people enrolled in Medicare and involve a handful of drugs at first. So for the time being, it will only benefit certain people. And it may be held up by litigation.

“So I don’t think it’s a good idea to put all our eggs in one basket.”

Consequently, some believe the state boards may function as laboratory experiments for further action by the federal government. The somewhat varying approaches taken by the different boards — the guidelines for determining which drugs should undergo cost reviews, the methods for evaluating affordability, the process for covering as many residents as possible — may be useful in Washington.

“The mission is obviously affordability,” explained Mark Miller, executive vice president of health care at Arnold Ventures, a philanthropy that provides research support and develops policy ideas on a range of issues, including prescription drug pricing. “Just getting a restraint on prices and improve access for a given population in a state is a goal, but it also informs the federal process” for lowering drug costs.

Whether Capitol Hill lawmakers pay close attention is uncertain. Congress is currently mired in division and dysfunction. And the Biden administration is focused on ensuring that the Inflation Reduction Act is successfully implemented while avoiding being derailed by lawsuits from drugmakers. Any effort to further tackle prescription drug costs appears unlikely for the moment.

That said, the recent state efforts gained notice on Wall Street. Typically, the prism through which federal and state actions are seen by the Street is the bottom line – the effect such programs have on pharmaceutical industry revenue. So the move by the Colorado board to include the Vertex cystic fibrosis treatment, which is a big seller for the company, prompted some analysts to pay close attention.

“Given the significant uptick in bills related to state prescription drug costs, we believe there is an appetite for drug price control at the state level that make it worth watching whether others follow Colorado’s example, though it may take a few years to play out,” RBC Capital Markets analyst Brian Abrahams wrote in a note to investors in late August.

Each board takes somewhat similar approaches. For instance, the Minnesota board will review select brand-name drugs or biologics for which the list price rose by more than 15% or more than \$2,000 during any 12-month period or course of treatment lasting under 12 months. There are other criteria, some of which pertain to generics, as well.

In Colorado, the board must identify brand-name drugs or biologic medicines with an initial list price of \$30,000 or more for a 12-month supply or for a course of treatment that runs less than 12 months. Alternately, the list price increased \$3,000 or more during the immediately preceding 12 months for a year’s supply or for a course of treatment that is less than 12 months. Other criteria apply to generics.

These stipulations were widely known for the past two years, but when the Colorado board selected its list of the first five drugs to review, Wall Street analysts were not the only ones to take notice. The boards are generally expected to focus on widely prescribed medicines, such as blood thinners or rheumatoid arthritis. But choosing the Vertex drug for cystic fibrosis prompted a new layer of debate.

The company sent us a statement saying that, in general, these boards “will hinder access to important life-saving medicines, particularly those for rare diseases like cystic fibrosis, while also curtailing investment in scientific innovation and drug discovery.” Vertex further argued that patients and doctors also believe that its drug, called Trikafta, should not have been chosen for review.

For its part, the Cystic Fibrosis Foundation has talked up the benefits of the treatment, a triple-combination therapy that is effective in about 90% of cystic fibrosis patients, but also carries a list price of about \$322,000. The patient group acknowledged a need to rein in drug costs, but [argued](#) any move to set an upper payment limit for the treatment could “come at the expense of patient access.”

On a broader level, such objections underscore concerns about how boards will handle rare disease drugs, which are approved to treat relatively small patient populations. Often, these medications carry high price tags, which the pharmaceutical industry maintains reflects the large investments needed to develop them. But this has placed them squarely in the debate over costs and affordability.

“The small number of patients in rare disease populations can create unique challenges for drug development and present different market considerations compared to other therapies,” the Cystic Fibrosis Foundation wrote earlier this week to Michigan lawmakers. The organization wants separate criteria to be established by the state board for rare disease drugs.

The process can go slowly, however.

The Michigan legislation would require a board to choose at least one drug to review within 18 months of forming. Four years after its creation, the Maryland board is expected to select drugs for review by January, but there are no hard dates, according to Andrew York, the board’s executive director. There is no set number of drugs to review, but he expects the first round will be up to five medicines.

A review is still under way in Colorado, where the board sifted through more than 600 drugs and relied on 17 data points for its selection. But the board cannot review more than 18 drugs during the first three years. As a result, much like the Inflation Reduction Act, there are limits on how many people may benefit, at least initially, as the boards proceed.

“The board doesn’t decide if a drug is affordable, it decides if it’s unaffordable,” explained Lila Cummings, Prescription Drug Affordability director. “If it is, then the board can choose to start the rule-making process” for establishing upper payment limits. But along with other state bills that address drug costs, “we think these are good policies... that can really bring competition back to the market.”

The pharmaceutical industry, meanwhile, is lobbying to limit the impact these boards may have. The Pharmaceutical Research and Manufacturers of America, an industry trade group, has argued the Colorado board used flawed methodology and an incomplete database for selecting drugs to review, and is rushing the process. In general, the trade group blames insurers for unaffordability.

“Prescription drug boards are government schemes in which patients may face significant barriers to life-saving medicines because of government price setting,” a PhRMA spokesman wrote. “These boards

allow politicians to assign unelected bureaucrats to arbitrarily decide which medicines will be available and the price of those medicines with little accountability or input from patients and their doctors.”

Such posturing suggests to some that the pharmaceutical industry will go to court in a bid to derail the board. In years past, industry trade groups aggressively battled other state efforts, such as laws designed to [provide more transparency](#) about industry costs and a Maryland law that attempt to curtail [price gouging](#).

Attorneys at Hyman, Phelps & McNamara, a law firm that specializes in pharmaceutical regulatory issues, wrote four months ago on its [FDA Law Blog](#) that the Minnesota law, for instance, could face legal challenges. State lawmakers might face lawsuits accusing the state of violating the U.S. Constitution — specifically, the commerce clause, which regulates interstate commerce.

But one expert believes the states are in a better position this time to deflect such efforts thanks to subsequent court rulings. For instance, the U.S. Supreme Court three years ago upheld an Arkansas law that governs reimbursements rates that pharmacy benefit managers must pay to pharmacies. A trade group unsuccessfully argued that the law was preempted in health plans regulated by a federal law known as the Employee Retirement Income Security Act, or ERISA.

“I think the states are well-positioned,” said Jane Horvath, a former health care policy strategist at Merck and a consultant who has previously worked with the National Academy for State Health Policy. The nonprofit works with state officials and lawmakers to develop programs to lower drug costs. “I don’t think boards have to worry about getting sued and losing.

“They hold a good hand of cards and there will be a lot of consumer pressure to keep costs low.”

### **Pharma companies and their allies seek to exempt orphan drugs from state pricing limits**

March 21, 2024

As more states create dedicated boards to cap the costs of medicines, some drugmakers and their allies are pushing back with a controversial tactic — lobbying for legislation to set exemptions for so-called orphan drugs, which are used to combat rare diseases that afflict relatively small groups of patients.

The efforts, which are being joined by some some lawmakers, reflect concerns that patients may lose access to these medicines if pharmaceutical companies halt sales or decide not to invest in developing such drugs. But opponents argue blanket exceptions would unnecessarily extend to numerous big-selling treatments for common conditions that — thanks to regulatory endorsements — also happen to have an orphan designation.

As a result, consumer advocates complain these legislative maneuvers, which have been proposed in several states, would only increase the risk that countless patients could have trouble paying for a wide variety of medicines. They further argue that the legislation would preserve profits for drug companies at the expense of states trying to cope with budgetary strains.

“The messages are filled with misinformation that is hard to set straight because it is such a complicated topic and patients are made to feel like their lives are at stake, because that’s how it’s been characterized,” said Jane Horvath, a former health care policy strategist at Merck and a consultant who works with state officials and lawmakers to develop programs to lower drug costs. “If you’re a legislator who thinks people will die, what do you do with that?”

The exemptions have usually been inserted into bills to establish prescription drug affordability boards, which are designed to function like a rate-setting authority. Most of the boards are seeking upper payment limits, or ceilings, for determining prices paid for medicines. In some states, the plan is to set prices paid not just by state and local governments, but also by commercial insurers operating there.

The boards were hatched in response to frustration with Washington over budgetary gaps caused by the rising costs of prescription medicines. So far, seven states have created a board, although some are further along than others and their approaches can vary toward guidelines for determining which drugs should undergo cost reviews and methods for evaluating affordability, for instance.

Still other states are exploring boards, and the trend has alarmed the pharmaceutical industry, which has often lobbied against their creation or sought to blunt their impact. Colorado, however, has been a key focus after the state board there last month became the first in the nation to [establish an upper payment limit](#) for a costly medication — a rheumatoid arthritis treatment called Enbrel.

This is where an exemption for orphan drugs has come into play.

The idea, which has been embraced by some patient advocacy groups, is to shield medicines that were approved by regulators for relatively small patient populations from any attempt to set a ceiling on prices. The Inflation Reduction Act, which allows Medicare to negotiate prices on certain drugs, exempts orphan drugs, although only when the drug is approved for treating just one rare disease ([see page 24](#)).

The orphan drug designation was created in a [1983 law](#) designed to provide companies with incentives to develop therapies for small patient populations with hard-to-treat rare diseases. The incentives are valuable and include seven years of market exclusivity for rare drugs, a 50% tax credit to cover the cost of clinical trials, and federal research grants.

in effect, a company wins an opportunity to corner the market and a handsome revenue stream, since the lack of competition can also provide more flexibility in setting a price. And Wall Street has recognized the potential. On average, the stock price of a company increased by almost 3.4% after an orphan designation, according to a [2017 study](#) in the Orphanet Journal of Rare Diseases.

But creating upper payment limits is prompting anxiety that some companies might balk at making their orphan drugs available. Their fears were nearly realized last fall when the board in Colorado reviewed a cystic fibrosis drug called Trikafta, which has a \$310,000 list price before any discounts. The board [ultimately decided](#) last December that the medicine was “not unaffordable.”

This happened, however, only after a strenuous lobbying campaign by the Cystic Fibrosis Foundation and numerous families, who submitted letters to the state board expressing concerns that the



manufacturer, Vertex Pharmaceuticals, might withdraw its medicine from the state. The company gave this impression in a letter submitted to the board last October as debate over Trikafta intensified.

Using stern language, Amit Sachdev, an executive vice president and chief patient officer, [wrote](#) that “as a consequence of the [board’s] rules, manufacturers subject to an upper payment limit may have no practical choice but to withdraw from Colorado, leaving patients on life-saving therapies with... increased barriers to access compared to similarly situated patients in other states.”

In Colorado, state lawmakers — concerned about [reduced patient access](#) and the possibility that drug companies might not pursue rare disease treatments — reacted by introducing a [standalone bill](#) to create exemptions for orphan drugs. In explaining the move, Colorado state Sen. Barbara Kirkmeyer, who co-sponsored a bill, recently testified that she was motivated by a relative with cystic fibrosis.

“I’m not here because of Big Pharma,” she [told a Senate committee](#) last month. “When the [board] holds up that drug for cystic fibrosis, it sends chills through people, because it stops research. It stops people from thinking, ‘When can I invest in... these types of drugs?... We’re not talking about changing the [board’s review] process. There are still thousands, thousands, of drugs they can look at.”

But opponents say the position taken by Vertex and the subsequent reaction by lawmakers amounts to saber-rattling. “It feels a little like blackmail,” said Bethany Pray, deputy director of the Colorado Center on Law and Policy. “The drug companies are saying we may take this drug away from you if we have to lower our price, and our support is contingent on prices remaining high.”

Nonetheless, legislators in other states have had similar thoughts. Exemptions were established in Oregon and Washington, according to Horvath, and have been proposed elsewhere, such as in [Connecticut](#) and [Kentucky](#), where lawmakers are looking to create affordability boards. But exemptions failed to gain traction in other states, such as Illinois, [Michigan](#), and [Virginia](#), that are pursuing affordability boards.

So far, the Colorado bill is winding its way through the state Senate and has [support from lobbyists](#) working on behalf of Vertex, Biogen, Bristol Myers Squibb, and Alexion Pharmaceuticals, which is a subsidiary of AstraZeneca, according to Colorado Capitol Watch, which tracks legislation. Numerous other drugmakers are also following its progress.

But the implications are starting to generate significant pushback thanks, in part, to the status of Enbrel, which is sold by Amgen and is undergoing an affordability review by the state board. In this case, there is a big wrinkle. Why? The medicine was approved by the Food and Drug Administration for large populations of patients who suffer from rheumatoid arthritis, psoriatic arthritis, and plaque psoriasis.

These are lucrative markets and Enbrel racked up more than \$3.6 billion in sales last year in the U.S. Notably, nearly 94% of the spending on the medicine was for those widely prescribed uses, according to a [2021 study](#) in Health Affairs. However, the medicine also has an orphan designation for treating a type of juvenile rheumatoid arthritis, which accounted for just 1.4% of spending.

Due to this one orphan designation, though, Enbrel would not be subject to affordability reviews by any state board — not just in Colorado — that creates blanket exemptions for orphan drugs. This is hardly the only example. A recently [published study](#) in Health Affairs found that, as of 2022, 65% of orphan drugs were approved for a single rare disease — and 20% were approved for both rare and common diseases.

For this reason, opponents argue that exemptions are a classic case of overreaching. “That’s quite a lot of drugs that could become exempt,” said Priya Telang of the Colorado Consumer Health Initiative, an advocacy group. “These exemptions would gut the work of the board just as it’s getting started. And we’re talking about some of the most expensive drugs in Colorado.”

The Enbrel treatment cost more than \$46,000 per year for each patient in 2022, according to a Colorado claims database. A [2020 investigation](#) by the U.S. House Committee on Oversight and Reform found that Amgen benefited from big price hikes, raising the price 27 times since acquiring the drug in 2002, which amounted to a 457% increase.

And U.S. patients have paid more than elsewhere. In 2017, Amgen charged \$4,442 for a one-month supply, roughly double the price in Germany and more than three times the price in Canada. And Amgen filed 57 patent applications on Enbrel in the U.S., with the aim of delaying competition by 39 years, according to a [2018 report](#) by the Initiative for Medicines, Access, and Knowledge.

In general, drugmakers have taken advantage of orphan designation to extract higher prices. Research published in JAMA last year found that drugs initially approved for a rare disease were just as lucrative as drugs developed for more common conditions. In six cases, orphan drugs were granted additional uses within five years and the prices charged were as high as for the original orphan indication.

For its part, [Amgen argued](#) last October that, in recent years, rebates paid to win favorable coverage by health plans have jumped by 65% and reduced its net pricing by nearly 5%. The company has also hired lobbyists to monitor the Colorado bill but has not publicly taken a position. An Amgen spokeswoman did not respond to questions about the orphan exemption.

Meanwhile, though, the other co-sponsor of the bill in the Colorado senate said she is now seeking to change the language. In response to the outcry over exemptions, state Sen. Joann Ginal told us she harbors concerns that too many expensive, widely prescribed medicines — which also happen to have an orphan designation — would become exempt from state efforts to control costs.

“If the orphan indication is the only indication, then I can understand” an exemption, said Ginal, who once worked as a medical science liaison at such large drug companies as Genentech, Bristol Myers Squibb, and Wyeth, which was bought by Pfizer. “But if there’s an orphan indication for a drug that has many indications for wider use, then I’m concerned.

“Look, I’m not trying to gouge out the work that [the board] would do. But I do know folks who have these rare diseases. They’re scared. They’re stressed. They’re concerned if [the price of a drug] does get capped that they may not get their medications. I don’t want to take that chance with this group of

people. I don't know whether companies would pull out or not but is it worth taking that chance? I hope they wouldn't, but that's where I'm at."

Whether any version of the legislation succeeds remains to be seen. The bill has still not gotten out of the Colorado senate. If it does, it must then pass muster in the House before going to Colorado Gov. Jared Polis. Meanwhile, the pharmaceutical industry continues to fight these boards more generally, but Colorado is getting particular attention after the first-in-the-nation decision to focus on Enbrel's affordability.

In a [blog post](#) last week, the Pharmaceutical Research & Manufacturers of America, the trade group, complained of a "flawed process" for determining affordability and argued Colorado is "rushing towards disastrous outcomes for patients who rely on life-saving medicines prescribed by their doctors." A PhRMA spokesman said the trade group has not taken an official position on the orphan drug exemption.

Clearly, the debate over the Colorado board — and the effort to limit its influence by creating exemptions — will set the tone for what could become similar wrangling in other states. And at least for the near term, these battles may represent the next great struggle to address the cost of prescription medicines in the U.S.

"They're going hard everywhere," said Miles Baker, chief of staff for the Committee to Protect Health Care, a national organization of health care professionals, "but really doubling down in Colorado because it's the furthest along."

## **Principal Illness Navigation (PIN), Community Health Integration (CHI), SDOH Assessment, and Caregiver Training Codes in Medicare Physician Fee Schedule**

### ***Medicare Learning Network on Navigation and Other Health Equity Services***

In January 2024, the Centers for Medicare & Medicaid Services (CMS) published a Medicare Learning Network article that describes the new health equity services codes and explains how CMS will pay for those services. The 14-page guide is available online: [MLN9201074 - Health Equity Services in the 2024 Physician Fee Schedule Final Rule \(cms.gov\)](#)

### ***Cancer Moonshot Actions to Make Navigation Services Easily Accessible***

On March 8, 2024, the White House announced specific actions taken and partnerships launched to advance the use of navigation and other health equity codes. Read the beginning of the Fact Sheet and find the implementation details online: <https://www.whitehouse.gov/ostp/news->

[updates/2024/03/08/fact-sheet-biden-cancer-moonshot-announces-commitments-from-leading-health-insurers-and-oncology-providers-to-make-navigation-services-accessible-to-more-than-150-million-americans/](https://www.whitehouse.gov/ostp/news-updates/2024/03/08/fact-sheet-biden-cancer-moonshot-announces-commitments-from-leading-health-insurers-and-oncology-providers-to-make-navigation-services-accessible-to-more-than-150-million-americans/),

MARCH 08, 2024

## **FACT SHEET: Biden Cancer Moonshot Announces Commitments from Leading Health Insurers and Oncology Providers to Make Navigation Services Accessible to More than 150 Million Americans**

Marking major progress on President Biden’s Unity Agenda, the Biden Cancer Moonshot secured new commitments from health plans and oncology providers to deliver important support services to more Americans living with complex health conditions, including cancer

Today, the Biden Cancer Moonshot announced new commitments from seven leading health insurance companies expanding access to navigation services to help patients and their families navigate health care treatments for cancer and other serious illnesses. These health insurers—Aetna, a CVS Health company; Blue Cross Blue Shield of Minnesota; Elevance Health; Health Alliance Plan; Humana; Priority Health; and Select Health—serve more than 150 million patients, nearly half of all Americans across the country. In addition, the Biden Cancer Moonshot announced 40 comprehensive cancer centers and community oncology practices nationwide who commit to using the new navigation codes to provide patient navigation services to people facing cancer.

Through the Biden Cancer Moonshot, President Biden and First Lady Jill Biden have prioritized supportive services for people who are touched by cancer, including by championing the importance of patient navigation services. Navigators guide families through every step of their cancer journey. Navigators have been shown to improve health outcomes and the patient experience by reducing times between diagnosis and treatment, and increasing treatment completion. These services also lower healthcare costs by reducing ER visits and hospitalizations and reduce health disparities, including by facilitating access to services to address unmet social determinants of health, such as food and housing insecurity and transportation needs. Until President Biden and Dr. Biden prioritized increasing these services, Medicare and other health plans largely did not pay for navigation, leaving this service out of reach for too many people, especially in low-resourced settings.

With leadership from First Lady Jill Biden, the Biden-Harris Administration announced that Medicare would begin paying for certain navigation services starting January 1, 2024. The Biden Cancer Moonshot also led efforts to update existing medical billing codes to enable commercial health insurers to pay for navigation services. The Cancer Moonshot’s efforts to update the billing codes and drive use among providers and insurers means, for the first time ever, millions of Americans will be able to access much-needed support, like clinical care coordination, health education, patient self-advocacy training, health system navigation, and connection to community-based social services to address food and housing insecurity, transportation needs, or other issues that could interfere with treatment.

Read the remainder of the White House Fact Sheet: <https://www.whitehouse.gov/ostp/news-updates/2024/03/08/fact-sheet-biden-cancer-moonshot-announces-commitments-from-leading->

[health-insurers-and-oncology-providers-to-make-navigation-services-accessible-to-more-than-150-million-americans/](#).

### ***White House Q&A Session on Navigation Codes***

On February 23, 2024, the White House held a question and answer session on the new Medicare physician fee schedule codes supporting navigation, community health integration, and assessment of social determinants of health. A read-out of the session summarizes the efforts of CMS and American Medical Association to encourage utilization of the codes. See the read-out: [Readout of White House Q&A Session on Navigation Codes | OSTP | The White House](#)