



A Look at Recent Proposals to Control Drug Spending by Medicare and its Beneficiaries

The affordability of prescription drugs is a pressing concern for many Americans, with broad agreement across the political spectrum that lowering prescription drug costs should be a top priority for Congress. The Trump Administration, members of Congress, and several 2020 presidential candidates have offered proposals to lower drug prices. Many of these proposals would affect prescription drug spending under Medicare, which accounts for **30 percent** of national retail spending on drugs and nearly \$1 out of every \$5 in total Medicare spending (Figure 1).

Prescription drugs are an important component of health care for Medicare beneficiaries,

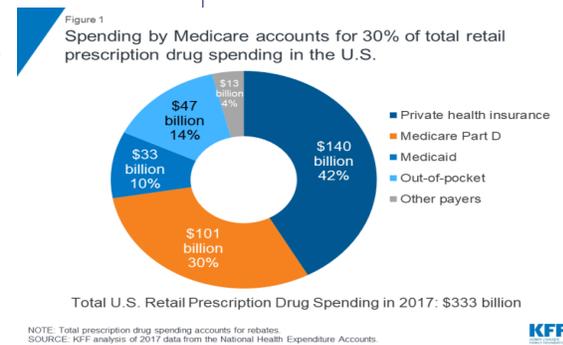
which includes more than 60 million older adults and people with long-term disabilities. The majority of Medicare prescription drug spending is for drugs covered under Part D, the outpatient prescription drug benefit. Medicare Part B also covers drugs that are administered to patients in physician offices and other outpatient settings.

This brief describes proposed and recent changes to control Medicare drug spending and lower beneficiaries' out-of-pocket drug costs. We include proposals from the Trump Administration and legislation introduced during the 116th Congress, including legislation that recently passed

out of the Senate Finance Committee. We review the implications of these changes for various stakeholders and explain their estimated effects on Medicare and beneficiary spending, to the extent such effects are known, based primarily on estimates from the Congressional Budget Office (CBO).

The brief focuses on drug pricing proposals related to Medicare specifically, rather than broader proposals that are not solely

focused on Medicare, including those related to drug importation, generic drug availability, patents, and price transparency.¹ While we have made every effort to include the most recent proposals pertaining to Medicare drug costs, policy discussions are evolving rapidly. This brief will be updated as necessary in the future... **Read More**



Retirees' budgets take a beating when prescription drug prices rise

Retirees' budgets take a beating when prescription drug prices rise faster than the annual cost – of – living adjustments (COLAs). But new legislation moving in the Senate would address that problem. The drug bill would require drug manufacturers to pay rebates when prices rise faster than inflation. Lobbying groups for drug manufacturers don't like the idea.

The Senate Finance Committee recently passed The Prescription Drug Pricing Reduction Act out of committee and now it heads to the floor for further action. The bill, which has support of both Democrats and Republicans would, among other things, cap drug prices based on the rate of inflation.

Medicaid already uses this strategy to lower drug costs, and

pays much lower prices than Medicare for the same drug. In June we **reported** that Medicare spending on the highest price category of prescription drugs, called "specialty drugs," increased from \$8.7 billion in 2010 to \$32.8 billion in 2015. Spending on the same drugs under Medicaid, the program that provides healthcare for low-income Americans, grew much more slowly over the same period, rising from \$4.8 billion to \$9.9 billion.

TSCL's surveys have found that moving Medicare Part D to a pricing system that has similarities with Medicaid has strong support among older adults. Seventy percent of those who participated in our **2019 Senior Survey** support allowing Medicare to negotiate prices for



prescription drugs using a similar system to Medicaid's.

The Senate bill also would change Medicare Part D by adding an out-of-pocket maximum for beneficiaries of \$3,100 starting in 2022. No such out-of-pocket cost cap currently exists. According to our 2019 Senior Survey, about one-in-five survey participants report out-of-pocket spending this high for prescription drugs. *Advisor* editor Mary Johnson estimates that this legislation would protect almost 14 million Medicare beneficiaries from out-of-pocket drug costs exceeding \$3,100 in the first year of enactment if signed into law.

In addition, the bill would help finance Part D benefits. The nonpartisan Congressional

Budget Office estimates the bill will save Medicare \$85 billion over a decade and save beneficiaries \$27 billion in out-of-pocket costs over the same period.

PhRMA, the drug industry's lobbying group, called the bill "the wrong approach to lowering prescription drug prices" and said it "imposes harmful price controls in Medicare Part D."

But with drug prices for many brand and specialty drugs running into the hundreds and even thousands of dollars for a single fill, TSCL believes that restricting the rate of increase on prescription drugs, and capping out-of-pocket costs, could help save lives and improve the health of older Americans.

How does Original Medicare cover inpatient services?



Dear Marci

Dear Marci,
I will be having my hip replaced this year, and my doctor told me I will need to stay in the hospital and then likely recover in a skilled nursing facility (SNF). I have Original Medicare. How does it cover inpatient services like this?
-Fiona (Culver City, CA)

Dear Fiona,

Inpatient hospital care and care in a skilled nursing facility (SNF) are both Medicare Part A-covered services.

Part A covers medically necessary inpatient hospital care, which is care that you receive as a formally admitted hospital inpatient. You must be formally admitted into the hospital by a physician in order for your care to be considered inpatient hospital care. You may face different costs if you are a hospital outpatient, meaning you receive services at the hospital but are not formally admitted.

If you are a hospital inpatient, Part A covers:

- ◆ A semi-private hospital room and meals
 - ◆ General nursing care
 - ◆ Medically necessary medications
 - ◆ Other hospital services and supplies
- Medicare does not cover:**
- ◆ Private duty nursing
 - ◆ A private room (unless medically necessary or if it is the only room available)
 - ◆ Personal care items (such as razors or socks)
 - ◆ A television or telephone in your room

After meeting your **Part A deductible**, Original Medicare pays in full for the first 60 days of your **benefit period**. After day 60, you will pay a daily hospital coinsurance. Part B continues to cover any outpatient provider services you receive while in the hospital. You usually owe a separate 20% coinsurance for these services.

SNF care is post-hospital care provided at a SNF.

Skilled nursing care includes services such as administration of medications, tube feedings, and wound care. Keep in mind

that SNFs can be part of nursing homes or hospitals.

Medicare Part A may cover your SNF care if:

- ◆ You were formally admitted as an inpatient to a hospital for at least three consecutive days
- ◆ You enter a Medicare-certified SNF within 30 days of leaving the hospital, and receive care for the same condition that you were treated for during your hospital stay
- ◆ And, you need skilled nursing care seven days per week or skilled therapy services at least five days per week

Note: the day you become an inpatient counts toward your three-day inpatient stay to qualify for Medicare-covered SNF care. However, the day you are discharged from the hospital does not count toward your qualifying days. Also remember that time spent receiving emergency room care or under observation status does not count toward the three-day hospital inpatient requirements for SNF coverage.

If you meet all of the above requirements, Medicare should cover the SNF care you need to

improve your condition, maintain your ability to function, or prevent your health from getting worse.

During a Medicare-covered SNF stay, Part A covers:

- ◆ A semi-private room and meals
- ◆ Skilled nursing care provided by nursing staff
- ◆ Therapy, including physical therapy, speech therapy, and occupational therapy
- ◆ Medical social services and dietary counseling
- ◆ Medications
- ◆ Medical equipment and supplies
- ◆ Ambulance transportation to the nearest provider or needed services, when other modes of transportation would endanger your health.

For each **benefit period**, Part A covers the full cost of your first 20 days in a SNF. For days 21-100, Part A covers part of the cost and you pay a daily coinsurance. If you need more than 100 days of SNF care in a benefit period, you will need to pay out of pocket.

-Marci

Feds take down alleged Medicare gene test fraud that peddled cheek swabs

WASHINGTON — Federal agents took down an alleged Medicare fraud scheme Friday that exploited seniors' curiosity about genetic medicine by enticing them to get their cheeks swabbed for unneeded DNA tests. Medicare was billed about \$2 billion.

Dubbed "**Operation Double Helix**," the crackdown targeted telemarketing companies, doctors, and labs, in a joint effort by the FBI, U.S. attorneys' offices, and the Health and Human Services inspector general. More than 30 people were charged around the country.

The alleged scam flourished at a time when many people are

getting DNA tests to trace back their family heritage.

Fraudsters preyed on people's fears of harboring genetic markers for diseases such as cancer. However, genetic testing is not routinely used to screen for cancer.

"A decade ago, it would have given Medicare beneficiaries pause if someone wanted to get a swab from their cheek of their saliva," said Shimon Richmond, who heads the inspector general's investigative division. "Today people know and recognize what (genetic testing) is, and they think 'I can get that done, and I can get it done for



free and find out if I have health issues that I need to address.'" It's a bad decision, said Richmond. Not only does it put the patient's Medicare ID in the

hands of fraudsters who can then keep reselling it for illicit purposes, but it can potentially compromise unique details of an individual's make-up.

Another downside: Medicare might deny future coverage for genetic testing when it's really needed, since the patient's record would show such an analysis was already done. Patients should only have genetic testing if their own doctor orders it, officials said.

The alleged scam worked like this: Officials said a telemarketing or in-person "recruiter" would convince a Medicare enrollee to take a genetic test, assuring them that the program would pay the full cost. The patient would provide their Medicare information. A doctor in league with the fraudsters would approve the test, and collect a kickback from the recruiter company. A lab participating in the scheme would run the test, bill Medicare, and share payments collected from the government with the recruiter. ... **Read More**

Medicare Part D plans often don't cover new generic drugs

According to **Stat**, the Association for Accessible Medicines—the trade association for generic drugmakers—issued a **report** revealing that less than half of new generic drugs are available to patients with Medicare Part D drug coverage. These drugs cost less than their brand-name drug equivalents and would save patients and taxpayers billions of dollars a year. **What's going on?**

Researchers studied the fate of the 115 newly FDA-approved generic drugs between 2016 and 2018. They found that in the first year after a new generic is approved, no more than one in four **Medicare Part D plans**, and as few as one in ten Part D plans, include the drug on their formularies, their list of covered drugs. In the second year, no more than one in three Medicare Part D plans include the drug on their formularies. It generally

takes close to three years before a new generic drug makes it onto half or two-thirds of Medicare Part D formularies.

Even after a new **generic drug** has been on the market for three years, about four in ten Medicare Part D plans do not include it on their formularies.

The report also indicates that Medicare Part D insurers that do cover these newly approved generic drugs tend to charge copays for them that are equivalent to brand-name drug copays. In fairness, some newly approved generic drugs cost almost as much as their brand-name equivalents. But, as a general rule, generic drugs should have lower copays than brand-name drugs.

In their second year on the market, generic drug prices tend to fall by around 45 percent. Still, only a small percentage of



Medicare Part D insurers—nine to 13 percent more—included new generic drugs on their list of covered drugs.

The Association for Accessible Medicines believes that the brand-name drugmakers are providing financial incentives to **Pharmacy Benefit Managers (PBMs)**—the middlemen who decide which drugs to put on a formulary—to exclude new generics from the Part D plan formulary. The brand-name drugmakers can legally do so, it appears. To increase their market share, they simply offer “**rebates**” or kickbacks to the PBMs if they do not cover the competitor generic drug.

The Association for Accessible Medicines also finds fault with the structure of the Medicare Part D drug benefit. At the point at which people fall into the coverage gap or “donut hole,”

brand-name drugmakers must offer a 70 percent discount on their drugs. But, the discount amount is included as part of the out-of-pocket costs people with Medicare must spend before Medicare covers 95 percent of costs. At that point, Part D plans have less liability for their drug costs. Consequently, Part D plans have a financial incentive to get people out of the donut hole by having them use brand-name drugs.

What's the solution? Congress should prohibit brand-name drug makers from providing financial incentives to PBMs and Part D plans to exclude coverage of generic drugs. Part D plans should be required to cover these generic drugs at generic drug copay levels. AAM claims people with Medicare would save \$4 billion a year from this fix; taxpayers would also save.

Next Social Security raise could be low, and that's not even the worst part

Social Security's cost-of-living adjustment, or COLA, likely won't rise much next year, but retirees may not feel any change — especially a positive one — at all.

The COLA for 2020 won't be announced until next month, but one analyst expects just a 1.6% adjustment next year, down from 2.8% in 2019. Mary Johnson, the Social Security and Medicare policy analyst at the Senior Citizens League, a nonpartisan advocacy group for retirees, has been tracking COLA since 1996. She anticipated the 2.8% adjustment for last year the month before the Social Security Administration announced its COLA (and estimated correctly).

The 1.6% adjustment would amount to roughly \$23 a month for someone receiving the average retirement benefit of \$1,460, Johnson said. COLAs have been averaging 1.4% over the last decade, half of the average 3% it was between 2000 and 2009. Last year's COLA was

the first big hike since 2012, when it was 3.6% (in 2018, COLA was 2%, and in 2017, it was 0.3%).

But the significant drop in COLA between 2019 and 2020 may not be the worst part. Social Security as it stands bases its adjustment on CPI-W, the consumer-price index and buying patterns of young workers. But young workers and retirees don't spend their money the same way.

“They will spend less on health care and perhaps housing, and those are the two expenses that really make a difference for older Americans,” Johnson said. Young workers might spend between 7% to 10% of their money on health care, compared with older Americans, who can expect to spend 12% to 25% on it, she noted.

Social Security benefits have already lost one-third of buying power since 2000, another Senior Citizens League study by Johnson found. The system as a

MarketWatch

whole could use some attention from politicians, who are still debating if and how to expand the program. The two trust funds that support Social Security are running out of money, and if Congress doesn't act, they can be depleted by 2035. If that were to happen, Social Security would be relying on money coming into the system as opposed to revenue and reserves to keep benefits afloat — and therefore, beneficiaries would receive only 80% of the checks they're owed.

Two of the fastest-growing expenses for retirees are out-of-pocket prescription drug expenses and Medicare Part B premiums, Johnson said, and the latter has the potential to wipe out any COLA increase at all for retirees. The Medicare Trustees expect a jump of almost \$9 more a month for the premium, compared with \$1.50 a month more beneficiaries paid between 2018 and 2019. That means

retirees receiving the average benefit will be left with about \$15 more a month from COLA, but people who receive less in benefits might not see an increase at all. There is a federal law that prohibits Medicare premiums from decreasing whatever benefit retirees already receive. If an increase is erased by premiums, however, it will only lessen buying power for retirees.

The expected COLA will also have a negative impact on lifetime Social Security benefits, especially for people who retired in 2009 because of the unprecedented low adjustments this last decade. Johnson estimates benefits for people who retired in 2009 are about 17.5% lower today than they would have been had inflation continued to average 3% in the last decade — the equivalent to more than \$17,000 in retirement income for someone who receives the average benefit, she said. That figure will only widen as time goes on.

CBO: Fix backed by doctors for surprise medical bills would cost billions

A Congressional Budget Office (CBO) analysis finds that a rival approach backed by doctors groups for protecting patients from getting massive “surprise” medical bills would increase the deficit by “double digit billions” of dollars.

The email from the nonpartisan CBO to a congressional office, obtained by The Hill, comes amid a raging debate over legislation to stop surprise medical bills, which is seen as a rare area of possible bipartisan accomplishment this year.

Powerful doctor and hospital groups are lobbying hard against the leading legislation, warning it would lead to damaging cuts to their payments.

But the newly obtained analysis from the CBO shows that the rival approach favored by the doctors and hospitals would carry a hefty price tag, in contrast to the leading

approach, which saves the government billions.

The CBO analysis could put a dent in doctors' and hospitals' efforts as they fight the surprise billing legislation.

The CBO looked at an approach that is featured in a bill from Reps. **Raul Ruiz** (D-Calif.) and **Phil Roe** (R-Tenn.), and backed by doctors, finding it would cost “double digit billions” of dollars over 10 years.

In contrast, the approach used in bipartisan bills that have passed out of the House Energy and Commerce Committee and the Senate Health Committee would both save more than \$20 billion over 10 years, the CBO has found.

The key difference between the approaches is in deciding how much the insurer will pay the doctor once the patient is protected.

The House Energy and Commerce and Senate Health



committee bills essentially set the payment rate that insurers will pay

doctors — based off of the median of the rates insurers have negotiated with doctors in that area.

In contrast, the Roe-Ruiz bill would give the decision to an outside arbitrator to decide the payment amount and instruct the arbitrator to consider the amount that doctors charge before any negotiation with insurers takes place, a much higher amount.

The CBO finds this Roe-Ruiz approach would drive up costs. The agency said that a similar approach in effect in New York state had increased payments to doctors “as much as 5 percent in response to the policy.”

“If payments to providers increased by 5 percent as the result of the policy, that change alone would result in a \$15 billion increase in the deficit over 10 years,” the CBO

wrote.

Roe contested the CBO’s conclusions in a statement to The Hill, saying premiums in New York have “actually fallen.”

“My biggest concern is we will enact a bad policy that makes the practice of medicine more difficult and more complex based on a score that is likely to be wrong because of how much it conflicts with real world practices,” Roe said. “I’m far more interested in enacting good policy that makes health care more patient centered than enacting a bad policy just because CBO estimates it will save more money.”

The path forward on which approach will win out remains unclear. The House Education and Labor Committee, which is also working on a bill, **delayed** a planned vote last week as some lawmakers push for the approach favored by doctors. There is still no agreement.

Medicare double-billed about 411,000 people who pay Part B premiums directly

Because of a “process error,” about 411,000 seniors who have their Medicare Part B premiums automatically deducted from their bank accounts through Medicare’s Easy Pay system were double-billed for the month of September, the Centers for Medicare and Medicaid Services said in a statement late Monday.

Jade Tippett of Fort Bragg noticed the error on Friday when he looked at his credit union checking account and spotted two withdrawals for \$135.50 each. When he called Medicare to ask about the double billing, “they said it may take until after Oct. 1 to fix it,” he said.

“Personally I can handle it, but people who are not where I am financially, those are the

people I’m concerned about.

This is \$135 a week before the end of the month. That could be people’s food budget for the rest of the month,” Tippett added.

“The Treasury Department is working to reverse the duplicate charge. Approximately 20% of the duplicated transactions have been returned by financial institutions, and if the remaining duplications are not returned by Wednesday, Sept. 25, Treasury’s Bureau of Fiscal Service will begin to reverse the remaining transactions to complete the reimbursement,” CMS said in a statement.

It added, “Beneficiaries concerned with overdraft or other fees related to the issue should contact their bank, and



ask that the fees be waived.

Beneficiaries

may contact 1-800-MEDICARE (800-633-4227), if verification that the issue occurred is needed.

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Neither CMS nor Medicare had announced the glitch on their websites as of Tuesday afternoon.

“We are exploring whether additional direct outreach (to those affected) is needed given that cases are being quickly resolved,” CMS said in a response to The Chronicle.... **Read More**

The Delicate Issue Of Taking Away A Senior's Smartphone

At first, Dr. Robert Zorowitz thought his 83-year-old mother was confused. She couldn't remember passwords to accounts on her computer. She would call and say programs had stopped working.

But over time, Zorowitz realized his mother — a highly intelligent woman who was comfortable with technology — was showing early signs of dementia.

Increasingly, families will encounter similar concerns as older adults become reliant on computers, cellphones and tablets: With cognitive impairment, these devices become difficult to use and, in some cases, problematic.

Computer skills may deteriorate even "before [older adults] misplace keys, forget names or display other more classic signs of early dementia," Zorowitz wrote recently on a group email list for geriatricians. (He's based in New York City and senior medical director for

Optum Inc., a health services company.)

"Deciding whether to block their access to their bank accounts, stocks and other online resources may present the same ethical dilemmas as taking away their car keys."

The emergence of this issue tracks the growing popularity of devices that let older adults communicate with friends and family via email, join interest groups on Facebook, visit virtually via Skype or FaceTime, and bank, shop, take courses or read publications online.

According to the [Pew Research Center](#), 73% of adults 65 and older used the Internet in 2019, up from 43% in 2010. And 42% of older adults owned smartphones in 2017, the latest year for which [data is available](#), up from 18% in 2013.

Already, some physicians are adapting to this new digital reality. At Johns Hopkins Medicine, Dr. Halima Amjad, an



assistant professor of medicine, now asks older patients if they use a computer or smartphone and are having trouble such as forgetting passwords or getting locked out of accounts.

"If there's a notable change in how someone is using technology," she said, "we would proceed with a more in-depth cognitive evaluation."

At Rush University's Alzheimer's Disease Center in Chicago, neurologist Dr. Neelum Aggarwal finds that older adults are bringing up problems with technology as a "non-threatening way to talk about trouble with thinking."

"Instead of saying, 'I have issues with my memory,' people will say, 'I just can't figure out my smartphone' or 'I was trying to start that computer program and it took forever to get that done.'"

If the person previously used digital devices without difficulty, Aggarwal will try to identify the

underlying problem. Does the older adult have problems with vision or coordination? Is she having trouble understanding language? Is memory becoming compromised? Is it hard for her to follow the steps needed to complete a transaction?

If using technology has become frustrating, Aggarwal recommends deleting apps on cellphones and programs on computers.

"The anxiety associated with 'Oh, my God, I have to use this and I don't know how' totally sets people back and undoes any gains that technology might offer," she said. "It's similar to what I do with medications: I'll help someone get rid of what's not needed and keep only what's really essential."

Typically, she said, she recommends no more than five to 10 cellphone apps for patients in these circumstances...[Read More](#)

Politics threatens drug pricing deal between Congress, Trump

A congressional effort to reach a deal to lower prescription drug prices this year seemed on a path to derailment Wednesday amid political escalation on several fronts.

House Republicans took a hard line against a [major plan](#) from House Speaker Nancy Pelosi (D-Calif.), in the first committee hearing on her proposal to authorize government negotiation of certain high-priced drugs.

Later in the afternoon, Senate Finance Committee Chair Chuck Grassley (R-Iowa) acknowledged his effort with ranking member Sen. Ron Wyden (D-Ore.) to get their [embattled proposal](#) on the Senate floor may not happen this year and could slip into early 2020 when the presidential election will overshadow congressional activity.

Grassley and Wyden planned to release the legislative text of

their legislation Wednesday, a necessary step to secure more GOP co-sponsors. Grassley said he won't meet with Senate Majority Leader Mitch McConnell (R-Ky.) about bringing the bill to the floor for a vote until he has more Republicans signed on in support.

But both the Senate and House face major hurdles to any substantial deal.

The House Energy & Commerce Committee's hearing on Pelosi's [plan](#) marked the first congressional debate over a signature idea from President Donald Trump: the [international price index](#).

But Republicans avoided specific mention of the president's idea as they panned the proposal to require Medicare price negotiation using an international



reference price as the ceiling.

Democratic panel leaders, on the other hand, underscored repeatedly how the speaker's proposal harnessed the White House's yet-to-be-finalized policy. Pelosi had also adopted the so-called "inflation caps" from the Grassley and Wyden Senate legislation, which would limit Medicare's allowed annual price increases to the rate of inflation. But that has drawn sharp criticism from Grassley's GOP colleagues.

"We all need to take a deep breath, roll our sleeves up and look for the opportunities to work together," Energy and Commerce health subcommittee chair Anna Eshoo (D-Calif.) said after a barrage of Republican complaints about Pelosi's bill.

As he left the hearing, House Energy and Commerce ranking

member Greg Walden (R-Ore.) declined to address Trump's international price index in detail, but noted "issues" with the rushed process between the release of Pelosi's bill and Wednesday's hearing that forestalled any serious consideration of the policy.

"If we get into the IPI and those issues, I want to know what the implications really are," he said.

He and other GOP members complained that the bipartisan work the committees were doing on a restructure of Medicare Part D similar to what the Senate Finance Committee proposed were effectively halted by the release of Pelosi's plan.

A source close to talks confirmed that the bipartisan work on Part D completely left out the Senate's inflation caps policy....[Read More](#)

OCTOBER IS BREAST CANCER AWARENESS MONTH

Breast cancer ... it's a scary thought and all too many women assume that it won't happen to them. Fact is though, every ten minutes a woman is diagnosed with breast cancer in the USA. So, don't be ignorant, during breast cancer awareness month 2019 go for a medical checkup, it might save your life.

Early signs of breast cancer can be a lump in a breast, a painful breast or armpit, or a discharge

from the nipple. Even if none of these symptoms present themselves, a doctor should be visited to be sure. A doctor will most likely perform a manual exam and send you for a mammogram. A mammogram examination is painless and only takes about ten minutes. If any of these symptoms do present themselves there's no



need to panic. Plenty of time, pain or a lump in a breast can be perfectly harmless. The pain can be a sign of a cyst or the lump can be benign. It's always better to be sure though.

If the mammogram shows a lump, your doctor will order a biopsy. This test will show if the lump is benign (harmless) or malignant (cancerous). If the

lump is cancerous there's still no reason to panic. Early detection is a life saver. By way of a simple operation the lump is removed after which the doctor will discuss further options with you.

If you've never had a mammogram, make an appointment during breast cancer awareness month 2019. You can take a friend or family member with you and afterward you'll have peace of mind.

You likely need more sleep than you think

As we age, we experience changes in sleep patterns. You might think you can get by with five or six hours of sleep every night. Believe it or not though, **adults need between seven and eight hours a night of sleep.** Sleep benefits both your mental and physical well-being.

According to sleep expert and NIH neuroscientist, Merrill Mitler, "Sleep services all aspects of our body in one way or another: molecular, energy balance, as well as intellectual

function, alertness and mood." A good night's sleep also improves your reflexes and overall ability to think clearly. An hour or two less than you need makes a difference in your level of reasoning, attention to detail, productivity and more.

Dr. Michael Twery, another NIH sleep expert, explains: "Sleep affects almost every tissue in our bodies. It affects growth and stress hormones, our immune system, appetite, breathing, blood



pressure and cardiovascular health." Some experts claim that sleep is **good for the brain** and can help extend your life.

As many as 70 million adults in America suffer from chronic sleep problems and do not get the sleep they need. Many people have **insomnia** and lay in bed awake a good chunk of the night. And, many people have **sleep apnea, which keeps them from sleeping soundly.**

Sleep apnea causes you to have a loud, uneven snore. And you may wake up gasping for air. Apnea can be dangerous, causing you to stop breathing for short periods and your blood pressure to spike. You are at higher risk of stroke.

Talk to your doctor if you have insomnia or the apnea symptoms. Sometimes, **exercising, losing weight** or sleeping on your side can reduce apnea symptoms. Do your best to get a good night's sleep. It matters!

In Tiny Doses, An Addiction Medication Moonlights As Treatment For Chronic Pain

Lori Pinkley, a 50-year-old from Kansas City, Mo., has struggled with puzzling chronic pain since she was 15.

She has had countless disappointing visits with doctors. Some said they couldn't help her. Others diagnosed her with everything from **fibromyalgia** to **lipedema** to the rare **Ehlers-Danlos syndrome.**

Pinkley has taken opioids a few times after surgeries, but they never helped her underlying pain, she said.

"I hate opioids with a passion," Pinkley said. "An absolute passion."

Recently she joined a growing group of patients using an outside-

the-box remedy: naltrexone. It is typically used to treat addiction to opioids or alcohol, in pill form or as a monthly shot.

As the medical establishment attempts a huge U-turn after two disastrous decades of pushing long-term opioid use for chronic pain, scientists have been struggling to develop safe, effective alternatives.

When naltrexone is used to treat addiction in pill form, it's prescribed at 50 milligrams. But chronic pain patients say it helps their pain at doses of less than a tenth of that.

Low-dose naltrexone has lurked for years on the fringes of medicine, and its zealous



advocates worry it may be stuck there. Naltrexone, which can be produced generically, is not even manufactured at the low doses that seem best for pain patients. Instead, patients go to compounding pharmacies or resort to DIY methods — YouTube videos and online support groups show people how to turn 50 mg pills into a low-dose liquid.

Some doctors prescribe it off label even though it's not FDA-approved for pain.

University of Kansas pain specialist **Dr. Andrea Nicol** recently started prescribing it to her patients, including Pinkley. Nicol explained that for

addiction patients it works by blocking opioid receptors — some of the brain's most important feel-good regions. So it prevents patients from feeling high and can help patients resist cravings. At low doses of about 4.5 mg, however, naltrexone seems to work differently.

"What it's felt to do is not shut down the system, but restore some balance to the opioid system," Nicol said.

Some of the hype over low-dose naltrexone has included some pretty extreme claims with limited research to back them, like using it to treat **multiple sclerosis** and neuropathic pain or even using it as a weight-loss drug. ...**Read More**

Do new cancer treatments offer meaningful benefits?

Stat News reports on a new **study, published in BMJ**, which finds that around 50 percent of the clinical trials for cancer treatments approved in Europe may not demonstrate meaningful benefits. Risk of bias in the design and reporting of clinical trials may mean that the drugs lack both therapeutic and financial value. Studies of **clinical trials for cancer drugs approved in the US** have similar flaws.

For the BMJ study, researchers looked at the strength of the evidence supporting new cancer drug approvals in Europe. They analyzed 54 **clinical trials** for the 32 cancer drugs approved

between 2014 and 2016. Of those with published studies, only one in four looked at overall survival rates. All the other trials, 29 out of 39, used “surrogate measures.” Surrogate measures cannot predict whether someone will live longer or enjoy a better quality of life. Some academics say they may undermine patient safety.

Researchers found that just about half (49 percent) of the published trials had a high risk of bias. They found a much higher risk of bias in the trials looking at surrogate measures of patient benefit (55 percent) than in the trials measuring overall



survival (20 percent). Note: Researchers found risk of bias, not actual bias.

Only 75 percent of the drug studies (41 of them) from 2014 to 2016 involved randomized, controlled trials. Just 27 of the 32 newly approved cancer drugs had a randomized trial. Between, 2009 and 2013, 90 percent of the studies involved randomized, controlled trials.

In addition, of the 32 drugs approved, 10 had problems identified by regulators. But, somehow, the regulators’ concerns about these drugs did not make it into the scientific literature.

The researchers recommend that clinical research for drugs be based on randomized trials and that these trials study data on meaningful outcomes, specifically overall survival. Without this research, it is hard to know whether new cancer drugs meet patients’ needs. It’s best to have a quality assessment of the evidence as well. Bias in clinical trial design is a serious issue.

The researchers also want more transparency from regulators. Patients should know the weaknesses of the research underlying a new drug and how these weaknesses might affect the trial results.

Do Not (And We Can't Stress This Enough) Press 1 If You Get This Call

You may get a call saying your social security benefits will be cancelled. Hang up.

A new scam call is going round. And it's so common, the Federal Trade Commission is warning people about it. This call tells you your social security benefits will be suspended and if you feel that's a mistake, press 1 on your keypad.

"The Social Security Administration never calls to threaten your benefits.

They'll never tell you to wire, send cash, or put money on a gift card.

If someone's calling you pretending to be them or asking for cash like that, it's a scam. Hang up."



Do not do it.

Once you hit 1 a scammer will pick up the phone and ask for your money or information.

Eligibility for ESRD Medicare (End Stage Renal Disease)

You may qualify for **ESRD Medicare** if you have been diagnosed with kidney failure and you:

- ◆ Are getting dialysis treatments or have had a kidney transplant
- ◆ And:
 - **You are eligible to receive SSDI**
 - **You are eligible to receive Railroad Retirement benefits**
 - **Or, you, a spouse, or a parent have paid Medicare taxes for a sufficient amount of time as specified by the Social Security Administration**

If you are under 65 and have ESRD, when your Medicare benefits begin depends on your specific **circumstances**, including when you apply for

Medicare, whether you receive dialysis at home or at a facility, and whether you get a kidney transplant. If you are eligible for ESRD Medicare, you can enroll in Parts A and B together at any time. Part A will be retroactive up to 12 months, but it cannot start earlier than the first month you were eligible for ESRD Medicare.

Note: If you are a railroad worker with ESRD, you must contact Social Security—not the Railroad Retirement Board—to find out if you are eligible for Medicare.

Because Social Security and Medicare eligibility rules are complex, it is recommended that



you call Social Security at 800-772-1213 to get the most accurate information regarding your particular situation.

Alert: 400,000 People Double-billed for Medicare Part B

Because of a “process error” **hundreds of thousands of retirees** who pay their Medicare Part B premiums directly were double billed for the month of September. The problem was announced by the Centers for Medicare and Medicaid Services (CMS) on September 24.

People who are older than 65 and on Medicare but aren’t receiving Social Security must

pay the premiums directly. Many have it withdrawn automatically every month from their checking or savings account through Easy Pay. Everyone in that group was double-billed.

CMS said it was working with the Treasury Department to correct the problem and advised beneficiaries who are concerned with overdraft or other fees related to the issue to contact their bank, and ask that the fees be waived. Beneficiaries may contact 1-800-MEDICARE (800-633-4227), if verification that the issue occurred is needed. CMS expects the situation to be corrected by October

Gene therapy shows promise repairing brain tissue damaged by stroke

It's a race against time when someone suffers a stroke caused by a blockage of a blood vessel supplying the brain. Unless clot-busting treatment is given within a few hours after symptoms appear, vast numbers of the brain's neurons die, often leading to paralysis or other disabilities. It would be great to have a way to replace those lost neurons. Thanks to gene therapy, some encouraging strides are now being made.

In a recent study in *Molecular Therapy*, researchers reported that, in their mouse and rat models of ischemic stroke, gene therapy could actually convert the brain's support cells into new, fully functional neurons.¹ Even better, after gaining the new neurons, the animals had improved motor and memory skills.

For the team led by Gong Chen, Penn State, University Park, the quest to replace lost neurons in the brain began about a decade ago. While searching for the right approach, Chen noticed other groups had learned to reprogram fibroblasts into stem cells and make replacement neural cells.

As innovative as this work was at the time, it was performed mostly in lab Petri dishes. Chen and his colleagues thought, why not reprogram cells already in the brain?

They turned their attention to the brain's billions of supportive glial cells. Unlike neurons, glial cells divide and replicate. They also are known to survive and activate following a brain injury, remaining at the wound and ultimately forming a scar. This same process had also been observed in the brain following many types of injury, including stroke and neurodegenerative conditions such as Alzheimer's disease.

To Chen's NIH-supported team, it looked like glial cells might be a perfect target for gene therapies to replace lost neurons. As reported about five years ago, the researchers were on the right track.²

The Chen team showed it was possible to reprogram glial cells in the brain into functional neurons. They succeeded using a genetically engineered retrovirus that delivered a single protein called NeuroD1. It's a neural transcription factor that switches genes on and off in neural cells and helps to determine their cell fate. The newly generated neurons were also capable of integrating into brain circuits to repair damaged tissue.

There was one major hitch: the NeuroD1 retroviral vector only reprogrammed actively



dividing glial cells. That suggested their strategy likely couldn't generate the large numbers of new cells needed to repair damaged brain tissue following a stroke.

Fast-forward a couple of years, and improved adeno-associated viral vectors (AAV) have emerged as a major alternative to retroviruses for gene therapy applications. This was exactly the breakthrough that the Chen team needed. The AAVs can reprogram glial cells whether they are dividing or not.

In the new study, Chen's team, led by post-doc Yu-Chen Chen, put this new gene therapy system to work, and the results are quite remarkable. In a mouse model of ischemic stroke, the researchers showed the treatment could regenerate about a third of the total lost neurons by preferentially targeting reactive, scar-forming glial cells. The conversion of those reactive glial cells into neurons also protected another third of the neurons from injury.

Studies in brain slices showed that the replacement neurons were fully functional and appeared to have made the needed neural connections in the brain. Importantly, their studies also showed that the NeuroD1 gene therapy led to marked

improvements in the functional recovery of the mice after a stroke.

In fact, several tests of their ability to make fine movements with their forelimbs showed about a 60% improvement within 20 to 60 days of receiving the NeuroD1 therapy. Together with study collaborator and NIH grantee Gregory Quirk, University of Puerto Rico, San Juan, they went on to show similar improvements in the ability of rats to recover from stroke-related deficits in memory.

While further study is needed, the findings in rodents offer encouraging evidence that treatments to repair the brain after a stroke or other injury may be on the horizon. In the meantime, the best strategy for limiting the number of neurons lost due to stroke is to recognize the signs and get to a well-equipped hospital or call 911 right away if you or a loved one experience them. Those signs include: sudden numbness or weakness of one side of the body; confusion; difficulty speaking, seeing, or walking; and a sudden, severe headache with unknown causes. Getting treatment for this kind of "brain attack" within four hours of the onset of symptoms can make all the difference in recovery.

Bill Would Eliminate Harmful Health Care Delays for People with Disabilities

Last week, Senator Bob Casey (D-PA), along with Representatives Lloyd Doggett (D-TX) and Brian Fitzpatrick (R-PA), introduced legislation to improve the health and economic security of people with disabilities—the Stop the Wait Act (**S. 2496, H.R. 4386**).

Currently, after waiting months to qualify for Social Security Disability Insurance (SSDI), most individuals with disabilities must wait an

additional five months before they can begin to receive benefits, and another two years before they are eligible for Medicare coverage. Only people with End-Stage Renal Disease and amyotrophic lateral sclerosis (ALS, or Lou Gehrig's disease) are excluded from the Medicare waiting period.

These delays mean that people with disabilities often cannot get



the help they need, when they need it, putting them at risk of worse health outcomes and high

out-of-pocket costs. The Stop the Wait Act would eliminate these dangerous waiting periods. It would require the Social Security Administration to begin payment to an individual eligible for SSDI immediately after they are determined to be eligible. It would also phase out

the 24-month waiting period for Medicare disability benefits.

In 2017, more than 10,000 Americans died while waiting for SSDI benefits to begin. Medicare Rights has long advocated for improving this broken system, and we strongly support the Stop the Wait Act. People with disabilities must not be forced to wait to access needed SSDI benefits and health care coverage.

[Read the Stop the Wait Act.](#)

The dangers of eye stroke

The eyes may be the window to the soul, but they're also home to our most dominant sense and can be harbingers of overall health and wellness. To keep them working well, they're fed by a vast network of blood vessels that bring oxygen to the delicate tissues of the eye. However, occasionally, the flow of oxygen-rich blood to the eyes can be blocked or interrupted. When this happens,

it results in a condition called eye stroke.

One of two areas of the eye are most commonly involved in eye stroke:

- The retina, which is a film at the back of the eye.
- The optic nerve, which transmits visual information from the retina to the brain for interpretation.



Barbara Horn, a doctor of optometry and president of the American Optometric Association says the

term "eye stroke is used to describe several different conditions that lead to vision loss because of lack of sufficient blood flow to the eye. An eye stroke can cause **sudden loss of vision.**"

Though the causes of these various types of eye stroke may

be different, the end result is the same: vision loss that can become permanent if it's not appropriately addressed as soon as possible.

The most common of these conditions include:

- ♦ **Retinal vein occlusion**
- ♦ **Retinal arterial occlusion**
- ♦ **Ischemic optic neuropathy**
- ♦ **Non-arteritic anterior ischemic optic neuropathy (NAION).** ...[Read More](#)

Older Diabetics May Be Getting Too Much Insulin

Are elderly people with diabetes being overtreated?

A new study suggests that's so: Older, sicker patients tend to be the ones most likely to still be using insulin to manage their blood sugar, despite guidelines that suggest it's often safer to lower diabetes treatment intensity with age.

The study found that nearly 20% of people with type 2 diabetes older than 75 were still using insulin treatment. And almost 30% of people with diabetes over 75 in poor health were taking insulin.

One of the most significant side effects of insulin is low blood sugar (hypoglycemia). This can leave you feeling shaky, sweaty, irritable, confused and dizzy. It can also cause an irregular heartbeat, and may lead to fainting. At its most serious, hypoglycemia can cause death, though this happens rarely, according to the American Diabetes Association.

Major health organizations -- including the American Diabetes Association, the U.S. Department of Veterans Affairs and the American Geriatrics Society -- recommend that healthy older patients can maintain tighter blood sugar control. But for patients in poor health, with shorter life expectancies, these groups suggest less aggressive

lowering of blood sugar levels.

"It seems a little counterintuitive after you spend decades working hard to control your blood sugar to think about not doing that," said study author Dr. Richard Grant.

"But, as with most things in medicine, there's a risk-benefit ratio, and for most years, there's a much bigger benefit than risk to taking insulin. But as life expectancy decreases, tight blood sugar control provides less benefit than risk," Grant said. He's a research scientist in the division of research at Kaiser Permanente of Northern California, in Oakland.

Grant said patients are often concerned if doctors bring up the idea of treating their diabetes less aggressively. "It's not abandoning care, it's maybe taking half a step back to reduce the risk from treatment," he explained.

The findings were published online Sept. 23 in *JAMA Internal Medicine*.

Another study published online Sept. 16 in the same journal found that patients don't always follow the guidelines for stepping down their treatment. The study -- led by Dr. Nancy Schoenborn at Johns Hopkins University School of Medicine in Baltimore -- found that 60% of people surveyed didn't agree



with the guidelines and thought the longer you live with diabetes, the more aggressive your treatment should

be.

These findings suggest that patients need better information about why doctors are recommending certain treatments plans over others, Schoenborn said in a university news release. Reducing treatment levels can lower the risk of side effects and improve quality of life, she said.

Grant's study included almost 22,000 people with type 2 diabetes. Their health was followed for up to four years, beginning at age 75.

Their health was defined as good if they had fewer than two additional medical conditions, or had two additional conditions but stayed physically active. Intermediate health was defined as having more than two additional conditions or having two additional conditions and no weekly exercise. People in poor health had end-stage lung, heart or kidney disease, or dementia or advanced cancer.

People in poor health had double the risk of being treated with insulin compared to those in good health. Those in intermediate health had an 85% higher risk of being treated with insulin than those in good

health, the findings showed.

Those most likely to continue using insulin throughout the four-year study were those in poor health. People in good health were least likely to stay on insulin.

Grant said, "It's very important for doctors to reassess the goals and treatment of older patients from time to time."

Dr. Joel Zonszein, director of the clinical diabetes center at Montefiore Medical Center in New York City, said, "We have to start thinking a bit more about how we treat elderly patients and the impact of treatment on their quality of life."

Zonszein said preventing low blood sugar levels (hypoglycemia) is even more important in older patients, and that there are newer types of insulin and other medications that can be used that have less risk of causing hypoglycemia.

The bottom line, according to the experts, is to maintain an ongoing conversation with your doctor. Anytime your health status changes, talk with your doctor about the benefits and risks of all the treatments you're taking.

More information

Learn more about living with diabetes as you age, from [Johns Hopkins Medicine](#).

FDA OKs New Pill for Type 2 Diabetes

A new pill to lower blood sugar for people with type 2 diabetes was approved by the U.S. Food and Drug Administration on Friday.

The drug, Rybelsus (semaglutide) is the first pill in a class of drugs called glucagon-like peptide (GLP-1) approved for use in the United States. Before Rybelsus, the drug had to be injected.

"Before this approval, patients did not have an oral GLP-1 option to treat their type 2 diabetes, and now patients will have a new option for treating type 2 diabetes without

injections," said Dr. Lisa Yanoff in an agency news release. She is acting director of the Division of Metabolism and Endocrinology Products in the FDA's Center for Drug Evaluation and Research.

GLP-1 is a hormone often found in low levels in people with type 2 diabetes. Rybelsus acts by slowing digestion and preventing the liver from making too much sugar, which helps the pancreas produce more insulin.

In clinical trials, Rybelsus significantly lowered blood



sugar. After 26 weeks, 77% of patients taking 14 mg of Rybelsus daily saw their HbA1C

drop below 7% compared with 31% among those receiving a placebo. HbA1C is a measure of blood sugar.

Rybelsus, made by the pharmaceutical company Novo Nordisk, is not recommended as the first choice for treating diabetes, the FDA said.

The drug has potential risks. It may cause certain thyroid tumors. Patients who have had thyroid cancer or have a relative

who has had it are advised not to take Rybelsus.

Rybelsus is also not for people with type 1 diabetes or diabetic ketoacidosis. The drug label also warns about inflammation of the pancreas, vision loss, low blood sugar and kidney injury.

The most common side effects are nausea, diarrhea, vomiting, decreased appetite, indigestion and constipation, the FDA noted.

More information

For more on type 2 diabetes, see the [American Diabetes Association](#).

How to Help Someone With PTSD

If someone in your life is struggling with post-traumatic stress disorder, you may wonder what to say or how to help. With PTSD, a disturbing event in the recent or distant past can cause intrusive memories, flashbacks and nightmares, unexpected outbursts, paralyzing fear and social avoidance. PTSD disrupts people's lives and relationships as it affects their ability to function.

PTSD can happen to anyone: Combat **veterans**, assault and abuse survivors, cancer patients, car crash victims, witnesses to natural disasters, police and emergency responders

repeatedly exposed to terrible situations or kids who have suddenly lost a family member or lived through **domestic violence**.

Although it shares similarities with **anxiety disorders**, PTSD is a stand-alone diagnosis. "The unique thing about PTSD is the person went through a traumatic event," says Jeremy Tyler, an assistant professor of clinical psychiatry at the Center for the Treatment and Study of Anxiety at University of Pennsylvania. "It's a disorder that has to do with how they respond to the trauma over time."

After someone goes through a



horrific event, it's quite common to have intense emotional symptoms for the next few months,

Tyler says. "We consider that to be pretty normal," he says. "PTSD is when those symptoms don't resolve."

Below, experts suggest supportive ways to respond if you learn a family member or friend is dealing with **PTSD**.

What It Looks Like

PTSD affects about 3.5% of U.S. adults and an estimated one in 11 people will be diagnosed with the disorder at some point, according to the American Psychiatric Association. It can

occur in people of any ethnicity, nationality, culture or age. Women are at higher risk than men, with double the likelihood of having the disorder.

Hallmarks of PTSD

A person with PTSD can experience the following symptoms soon after or long past the traumatic exposure or event:

Intrusive memories of the event.

- ◆ **Avoidance.**
 - ◆ **Behavior changes**
 - ◆ **Negative feelings and thoughts**
-[Read More](#)

95% of people think they could develop dementia with age

A global study on attitudes toward dementia has shown that two-thirds of people believe it to be a natural risk of getting older, which could be limiting the help that people seek.

Every **3 seconds**, someone develops **dementia** somewhere in the world. In the United States alone, **5.8 million** people are living with Alzheimer's, and every 65 seconds, another person develops the disease.

Alzheimer's is the sixth leading cause of death in the

U.S., beating breast and **prostate cancer** together, and it is one of the world's fastest growing causes of death. According to Alzheimer's Disease International (ADI), the number of people living with dementia is likely **to triple** from the current 50 million to 152 million by 2050.

Despite the prevalence of this neurodegenerative disorder, the world's largest survey of



attitudes toward it has shown that there is very little true understanding across the globe, even among healthcare professionals.

The study, which surveyed 70,000 people in 155 countries, found that 62% of healthcare professionals also believe that dementia is a normal part of aging.

The findings also revealed that only 16% of people are getting regular cognitive assessments,

even though early diagnosis can help.

The researchers found that almost 48% of the survey respondents believe that the memory of someone with dementia will never improve, even with medical help, while a quarter of respondents feel that there is no way to prevent this disease from developing....[Read More](#)