

May 8, 2022 E-Newsletter

Message from the Alliance *for* Retired Americans Leaders



AGE MY WAY: MAY 2022

May is Older Americans Month!



Robert Roach, Jr.
 President, ARA

Every May is Older Americans Month and this year's theme, Age My Way, provides an opportunity to explore the many

ways older adults can remain safe and involved with their communities.

The Alliance encourages everyone to make themselves aware of the work of the Administration for Community Living (ACL), part of the United States Department of Health and Human Services (HHS), which focuses on how older adults can plan to stay in their homes and live independently in their communities as long as possible.

Planning, participation, accessibility, and making connections all play a role in aging in place. The National Institute on Aging, also part of HHS, has a web page which gives advice on how to plan to age in place if that is your preference.

"It is important to remember that every senior's needs and preferences are unique, but wanting to age in place remains a goal for the majority of older Americans," said Robert Roach, Jr., President of the Alliance. "However, aging in place can carry risks and challenges, from falls to transportation issues. Planning ahead is important to prevent health problems and ensure that older people can enjoy the benefits of staying in their homes and communities

Sen. Warren, Experts Highlight Executive Actions to Lower Drug Prices



Rich Fiesta,
 Executive Director, ARA

In a letter to HHS Secretary Xavier Becerra, Senator Elizabeth Warren (MA) outlined a number of executive actions that the Biden administration could take to lower the cost of prescription drugs.

Backed by legal and medical experts from Yale Law School, Harvard Medical School and Columbia Law School, the Senator provided an extensive list of options for lowering drug prices without additional Congressional intervention.

Sen. Warren mentions 'government patent use power,'

as one action the Executive branch could take. This option formalizes the government's ability to use any "invention described in and covered by a patent of the United States" without a license, provided that the use is "by or for the United States" and the patent holder is afforded "reasonable and entire compensation." As recently as the 1960s and 1970s, federal agencies used government patent use power to procure low-cost versions of patented medicines.

Other possible actions come by way of the Bayh-Dole Act's "royalty-free license" and "march-in rights." Adopted in 1980, the Bayh-Dole Act was intended to ensure that the public would not be deprived of the benefits of inventions that it had effectively sponsored through government-funded research.

Royalty-free licenses to covered patents permit the government to manufacture drugs for its own use or license production on the government's behalf. Sen. Warren writes that the plain text and statutory purpose of the Bayh-Dole Act make a strong case that this option encompasses production of drugs for use by government programs such as Medicare and Medicaid.

March-in licenses can be

authorized if a patent holder has not taken "effective steps" to "achieve practical application" of a drug or if "action is necessary to alleviate health or safety needs which are not reasonably satisfied" by the patent holder. Sen. Warren writes that excessive pricing alone should provide sufficient grounds for exercising march-in rights.

"As important as these Administrative actions are, these recommendations are not a substitute for strong Congressional action. Congress must put the needs of patients first, and pass legislation curbing the pharmaceutical industry's monopoly power and allowing Medicare to negotiate lower prescription drug prices. A cap on the price of insulin is also important," said Richard Fiesta, Executive Director of the Alliance. "Americans continue to pay the highest prices in the world for prescription drugs, and comprehensive action is needed."



From the Rhode Island Alliance for Retired Americans to it's members & All Mother's Happy Mother's Day

ADD YOUR NAME

Get The Message Out: SIGN THE GPO/WEP PETITION!!!!



**Time is running out. Only one week left
to register to help support the
the Task Force to repeal the WEP/GPO**



**NATIONAL WEP/GPO REPEAL TASK FORCE
DAY OF ACTION & RALLY IN WASHINGTON, DC
May 18, 2022. 8 AM - 5 PM.
Rally from 11:30 AM - 1 PM**

The Rhode Island Alliance *for* Retired Americans will meet with:

Senator Jack Reed at 2 p.m.

Senator Sheldon Whitehouse at 1:30 pm

Congressman James Langevin at 4 p.m.

Congressman David Cicilline at 10:30 a.m.



For more information and to register by May 18th, go to

www.ri-ara.org

or sign up at

[Sign up for the WEP/GPO Day of Action](https://www.facebook.com/groups/354516807278/)

[Washington D.C.](https://www.facebook.com/groups/354516807278/)

No Votes on Health Care or Social Security Issues This Week

After having come back in session after a two-week break, the House of Representatives is out of session again this week for a district work period. That means the members of the House are back in their districts meeting with constituents. It is a good time for you to call one of their district offices and try to arrange a meeting with your Representatives to express your concerns.

The Senate is in session this week but there are no votes scheduled on health care or Social Security issues.

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Biden Administration Issues New Rule to Help Lower Drug Costs

With the legislation to lower drug costs stalled in Congress and its fate uncertain, last week the Biden Administration took action that it hopes will lower drug costs for many seniors.

Under a final rule issued last Friday, seniors enrolled in Medicare Advantage plans and

Medicare Part D prescription drug plans can expect improved transparency and lower out-of-pocket costs for medications by requiring Medicare prescription drug plans to pass certain savings on to customers.

More Medicare Part D drug plans are entering “price concession” arrangements in which they pay reduced costs to some pharmacies for certain dispensed drugs. But these arrangements are not publicly disclosed, and the drug plans do not pass the savings along to Medicare patients who purchase the drugs.

The new rule requires Part D plans to give all price reductions they receive from network pharmacies to the person buying the drug, which should reduce the out-of-pocket cost charged to the customer. The policy will take effect on Jan. 1, 2024.

The delay in the starting date of the new rule is to give the Part D plans time to adjust their pharmacy contracting and avoid any possible disruptions.



However, the insurance companies that offer the Part D plans are not happy. They say that only pharmacists will benefit from this requirement, with seniors and taxpayers paying the price through higher premiums.

The final rule also requires, among other things, private Medicare Advantage plans to streamline the grievance and appeals processes in certain cases for those who are “dual-eligibles,” who are seniors who qualify for both Medicare and Medicaid. The rule makes a change in Medicare Advantage plans’ co-payment rules that would result in more equitable payments to health-care providers who serve dual-eligibles.

The rule also includes a new maximum out-of-pocket policy for dual-eligible beneficiaries for Medicare Part A hospital services and for Part B outpatient services.

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The Windfall Elimination Provision and the Government Pension Offset

The Windfall Elimination Provision and the Government Pension Offset are two provisions that unfairly reduce or even eliminate the Social Security benefits of millions of Americans who have devoted their careers to public service, as well as having worked other jobs that withheld payroll taxes from their wages for Social Security benefits.

In January of 2021, bipartisan legislation, the Social Security Fairness Act (H.R. 82) which would eliminate the WEP and the GPO was introduced by Rep. Rodney Davis (IL) and Abigail Spanberger (VA). **To date the bill has 270 co-sponsors including BOTH Democrats and Republicans.** TSCL strongly endorses this legislation, and we are asking that you contact your Member of Congress and ask them to support the legislation too! If they already do, say thank you! If they do not, remind them that an election is coming up and you’ll be taking this issue into consideration when you cast your ballot.

Can Congress incentivize drugmakers to lower insulin prices voluntarily?

Senators Jeanne Shaheen and Susan Collins think they have a way to bring down the price of insulin without needing to pass legislation regulating its price. **Stat News** reports that their proposal takes into consideration that drugmakers must pay insurers to give their drugs preferential treatment, driving up drug prices. It also assumes that drugmakers would voluntarily lower their list prices if legislation frees them from paying insurers. Really?

The Shaheen-Collins proposal would forbid pharmaceutical companies from paying insurers for preferential treatment. It would also limit people’s monthly out-of-pocket insulin costs. It would only impose an out-of-pocket limit if insulin makers lowered their prices to \$68 a vial, its 2006 price. It now costs \$300 or so a vial.

Shaheen and Collins don’t know whether manufacturers would agree to their proposal. If

not, some people with insurance would still benefit as the proposal would require insurers to offer at least one insulin product for \$35 out-of-pocket a month. However, people with diabetes need to use different insulin products, so that backstop would only benefit people who needed the particular insulin product with an out-of-pocket cap.

Today, people with Medicare already have the option of capping their monthly insulin costs at \$35 through their Part D drug plans. That said, about one in four of them still paid more than \$35 a month for their insulin. Some other people with insurance also benefit from an out-of-pocket insulin cap.

Still, many people’s out-of-pocket costs with insulin each month can be more than \$150. At least one in four people who need insulin are paying more than \$35 a month for it.



The Shaheen-Collins proposal would only help people who are uninsured if

manufacturers lowered their list prices. And, if they most likely they would only do so voluntarily if the amount they no longer paid insurers to include their products on their formularies exceeded the difference between what they charge now for insulin and what they charged in 2006.

Most large advocacy groups think the Shaheen-Collins proposal is ridiculous. Drug manufacturers are not going to lower their prices voluntarily. And, if they don’t, their proposal would cost the federal government billions. It would also increase health insurance premiums for everyone as insurers would not eat the cost of a \$35 monthly out-of-pocket limit, they would shift it. Moreover, the proposal would encourage insulin manufacturers

to raise their prices further without fear that patients could not afford them.

Congress needs to pass legislation that lowers all drug prices for everyone. In the meantime, for lower drug prices, check out **Mark Cuban’s cost plus** discounted drug pharmacy. You might also check out pharmacychecker.com for verified pharmacies selling drugs at far lower rates than in the US. And, then, there’s always the opportunity to **pick up low-cost drugs on a trip** to Mexico, Canada, Japan or Australia, among many other countries.

Here’s more:

- ◆ **[One billionaire’s influence over lowering drug prices](#)**
- ◆ **[Millions safely import low-cost drugs from abroad](#)**
- ◆ **[How to ensure the drugs you take are safe and effective](#)**
- ◆ **[2022: Programs that lower your health care costs if you have Medicare](#)**

Medicare Advantage Plans Often Deny Coverage for Eligible, Necessary Care

Coverage for eligible, necessary care is denied each year to tens of thousands of seniors with private Medicare Advantage plans, U.S. federal investigators say.

In a **report** released Thursday, the team from the inspector general's office of the U.S. Department of Health and Human Services said Medicare needs to improve oversight of these plans and strengthen enforcement against those private insurance companies with a pattern of improper denials of coverage.

About 28 million older people have **Medicare Advantage** plans, which offer privatized versions of Medicare that are often cheaper and provide a greater range of benefits than the traditional government program.

But the HHS findings challenge claims by the industry's main trade group that Medicare Advantage "delivers better services, better access to care and better value."

Instead, the investigators said they found "widespread and

persistent problems related to inappropriate denials of services and payment."

Their review of 430 denials by Medicare Advantage plans in June 2019 revealed that 13% of cases where care was denied for medical services were actually medically necessary and should have been covered. Based on that rate, the investigators estimated as many as 85,000 requests for prior authorization of medical care were potentially improperly denied in 2019.

The report also said that Advantage plans refused to pay about 18% of legitimate claims, about 1.5 million payments, in 2019. In some cases, plans ignored prior authorizations or other documentation to support the payment.

The most frequent denials included those for **MRIs** and **CT scans**. In one case, an Advantage plan refused to approve a follow-up MRI to determine whether a lesion was malignant after it was identified through an earlier CT scan because the lesion was too small. The plan reversed its



decision after an appeal, the *New York Times* reported.

In another case, a patient had to wait five weeks

before authorization to get a CT scan to assess her endometrial cancer and determine a course of treatment. Such delayed care can threaten a patient's health, the report noted.

But Advantage plans also denied requests to send patients recovering from a hospital stay to a skilled nursing facility or rehabilitation center when doctors determined those places were more appropriate than sending a patient home, the *Times* said.

For example, a patient with bedsores and a bacterial skin infection was denied a transfer to a skilled nursing center, investigators found, while a high-risk patient recovering from surgery to repair a fractured femur was denied admission to a rehab center.

Clearly, these denials may delay or prevent a Medicare Advantage beneficiary from receiving needed care, according

to report team leader Rosemary Bartholomew. Few patients or providers try to appeal these decisions, she noted.

"We're also concerned that beneficiaries may not be aware of the greater barriers," Bartholomew told the *Times*.

A 2018 **report** by the HHS inspector general's office found that private plans reversed about three-quarters of their denials on appeal.

Hospitals and doctors have long sounded off about insurance company tactics, and legislation to tackle some of those concerns is being considered by Congress, according to the *Times*.

The report's findings are being reviewed to determine appropriate action, and plans with repeated violations will face increasing penalties, Medicare officials said in a statement, the *Times* reported.

They said the agency "is committed to ensuring that people with Medicare Advantage have timely access to medically necessary care."

Medicare Surprise: Drug Plan Prices Touted During Open Enrollment Can Rise Within a Month

Something strange happened between the time Linda Griffith signed up for a new Medicare prescription drug plan during last fall's enrollment period and when she tried to fill her first prescription in January.

She picked a Humana drug plan for its low prices, with help from her longtime insurance agent and Medicare's Plan Finder, an online pricing tool for comparing a dizzying array of options. But instead of the \$70.09 she expected to pay for her dextroamphetamine, used to treat attention-deficit/hyperactivity disorder, her pharmacist told her she owed \$275.90.

"I didn't pick it up because I thought something was wrong," said Griffith, 73, a retired construction company accountant who lives in the Northern California town of Weaverville.

"To me, when you purchase a plan, you have an implied

contract," she said. "I say I will pay the premium on time for this plan. And they're going to make sure I get the drug for a certain amount."

But it often doesn't work that way. As early as three weeks after Medicare's drug plan enrollment period ends on Dec. 7, insurance plans can change what they charge members for drugs — and they can do it repeatedly. Griffith's prescription out-of-pocket cost has varied each month, and through March, she has already paid \$433 more than she expected to.

A **recent analysis** by AARP, which is lobbying Congress to pass legislation to control drug prices, compared drugmakers' list prices between the end of December 2021 — shortly after the Dec. 7 sign-up deadline — and the end of January 2022, just a month after new Medicare drug plans began. Researchers



found that the list prices for the 75 brand-name drugs most frequently prescribed to Medicare beneficiaries had risen as much as 8%.

Medicare officials acknowledge that manufacturers' prices and the out-of-pocket costs charged by an insurer can fluctuate. "Your plan may raise the copayment or coinsurance you pay for a particular drug when the manufacturer raises their price, or when a plan starts to offer a generic form of a drug," the **Medicare website** warns.

But no matter how high the prices go, most plan members can't switch to cheaper plans after Jan. 1, said Fred Riccardi, president of the **Medicare Rights Center**, which helps seniors access Medicare benefits.

Drug manufacturers usually change the list price for drugs in January and occasionally again

in July, "but they can increase prices more often," said **Stacie Dusetzina**, an associate professor of health policy at Vanderbilt University and a member of the Medicare Payment Advisory Commission. That's true for any health insurance policy, not just Medicare drug plans. Like a car's sticker price, a drug's list price is the starting point for negotiating discounts — in this case, between insurers or their pharmacy benefit managers and drug manufacturers. If the list price goes up, the amount the plan member pays may go up, too, she said.

The discounts that insurers or their pharmacy benefit managers receive "don't typically translate into lower prices at the pharmacy counter," she said. "Instead, these savings are used to reduce premiums or slow premium growth for all beneficiaries."...**Read More**

Exclusive: oil companies' profits soared to \$174bn this year as US gas prices rose

Exxon, Chevron, Shell and BP among group of 24 who resisted calls to increase production but doled out shareholder dividends

The largest oil and gas companies made a combined \$174bn in profits in the first nine months of the year as gasoline prices climbed in the US, according to a new report.

The bumper profit totals, provided exclusively to the Guardian, show that in the third quarter of 2021 alone, 24 top oil and gas companies made more than \$74bn in net income. From January to September, the net income of the group, which

includes Exxon, Chevron, Shell and BP, was \$174bn.

Exxon alone **posted** a net income of \$6.75bn in the third quarter, its highest profit since 2017, and has seen its revenue jump by 60% on the same period last year. The company credited the rising cost of oil for bolstering these profits, as did BP, which made \$3.3bn in third-quarter profit. "Rising commodity prices certainly helped," Bernard Looney, chief executive of BP, told investors at the latest earnings report.

Gasoline prices have hit a seven-year high in the US due to



the rising cost of oil, with Americans **now paying** about \$3.40 for a gallon of fuel compared with around \$2.10 a year ago.

The Biden administration has warned the price hikes are hurting low-income people, even as it attempts to implement a climate agenda that would see America move away from fossil fuels, and has released 50m barrels of oil from the national strategic reserve to help dampen costs.

But oil and gas companies have shown little willingness so far to ramp up production to help reduce costs and the new report,

by the government watchdog group Accountable.US, accuses them of "taking advantage of bloated prices, fleecing American families along the way" amid ongoing fallout from the Covid-19 pandemic.

"Americans looking for someone to blame for the pain they experience at the pump need look no further than the wealthy oil and gas company executives who choose to line their own pockets rather than lower gas prices with the billions of dollars in profit big oil rakes in month after month," said Kyle Herrig, president of Accountable.US...[Read More](#)

Is There Any Way to Retire Comfortably on Social Security Alone?

The tricky thing about retirement planning is that it's hard to anticipate what your living costs will look like 15, 20, or 30 years down the line.

Maybe you'll end up spending \$1,000 a month on healthcare due to rising costs and multiple medical issues. Or maybe you won't even spend half that much.

But while it's difficult to estimate your retirement costs when that milestone is decades away, there are steps you can take to plan for your senior years, like socking money away in savings and establishing an income strategy. And part of the latter should include figuring out what role **Social Security** might play in your retirement.

Now many seniors depend on Social Security for the bulk of their retirement income. Some even count on those benefits to pay *all* of their living costs once

they stop working.

It may be possible for you to get by on Social Security alone. But whether that makes for an enjoyable retirement is a different story.

What do you want retirement to look like?

The average senior on Social Security today collects **\$1,663 a month**. Now the monthly benefit you receive may be higher, lower, or comparable. The sum Social Security pays you each month will hinge on factors that include:

- ◆ Your wage history, including the number of years you worked.
- ◆ Your Social Security filing age.

If you're a higher earner, you may be in line for a monthly benefit that's far more generous than \$1,663. Furthermore, if you



delay your filing beyond full

retirement age, you can boost your monthly benefit by 8% a year in the process, up until age 70.

So, let's say you're entitled to a monthly benefit of \$3,300 due to having earned higher wages and due to delaying your filing. If you have modest goals for retirement, a paid-off home, and no major health issues, then you might manage to live comfortably on that sum.

But if you're looking at a monthly benefit that's closer to what the average senior today collects, it's a different story. Even if you're content staying close to home and you're mortgage-free, being limited to \$1,663 a month could mean having to skimp on basic luxuries, like cable, to cover your essential bills. And that

sounds like the opposite of comfortable.

The point, therefore, is that while it may be possible for some people to maintain a decent standard of living using only Social Security as an income source, that's generally not advisable. A better bet is to make an effort to build a **nest egg** of your own so you have income to supplement those benefits with.

If you were to sock away \$300 a month in a retirement plan over 30 years, and your investments were to generate an average annual 8% return, which is a bit below the stock market's average, you'd wind up with about \$544,000. And that, combined even with an average Social Security benefit, could leave you with enough money to enjoy the comfortable senior lifestyle you deserve.

Can Social Security Be Grossed Up?

If you're a retiree who depends on Social Security, in some cases you can gross up your Social Security income on financial paperwork. You would do this to make your income more accurately represent the equivalent amount of earned income when it comes to qualifying for loans or other financial programs. This depends entirely on the third parties that you're dealing with, but it is not uncommon.

What Is Grossing Up?

"Grossing up" is adjusting someone's income to account for the taxes that they'll pay on it. The term comes from the fact that you adjust someone's net income (the amount they receive after taxes) to equal their gross income (the amount they receive on paper). It generally can be used in two different contexts. Firstly, someone making payments can "gross up" the recipient's income. In this case the payer



would compensate for the recipient's **taxes**, so that someone's on-paper income equals their

actual take home pay.

For example, say that Elizabeth earns \$80,000 per year. This is her gross pay. After income and **payroll taxes**, she would typically take home approximately \$59,500. This is her net pay. If Elizabeth's employer wanted to gross up her pay, they could add another \$20,500 per year to her

paycheck. In this case, Elizabeth would earn both \$80,000 per year gross and \$80,000 per year net.

Secondly, someone receiving non-taxable income can "gross up" their income by adjusting it upward when applying for financial products like loans and credit cards. This allows them to present their income in the same format as earned income...[Read More](#)

What To Know About Social Security When You're Past Retirement Age

If you're already past retirement age, there's not a lot you can do to modify your Social Security payments. However, there are still some factors that can boost your payout. At this age, it's also important to understand exactly how payouts for Social Security work, when they arrive, how they're taxed and how they may change in the future. Here's a quick overview of what you'll need to know about Social Security when you're past retirement age.

You Can Only Increase Your Payment Until Age 70

Once you've filed for Social Security, you can no longer increase your payments by earning more money or delaying your filing date. However, if

you're past retirement age but have not yet filed, your payment will increase every year you wait until age 70. The gains can be quite substantial, as your monthly income will rise 8% per year between age 67 and 70. But once you reach age 70, your payments stop increasing.

However, the US Government Can

You may not be able to increase your Social Security payments after age 70, but the U.S. government can. Every year, Social Security payments are subject to a cost-of-living adjustment in line with inflation. While in some years this adjustment amounts to zero, for 2022, payments jumped a



significant 5.9%. With inflation remaining stubbornly high through the first third of 2022, Social Security recipients could be in line for another big adjustment upward in January 2023.

Your Payments Arrive at the Same Time Every Month

Social Security benefits are paid in the month after they are due. For example, if you file to start benefits in August, your first check will arrive in September. The date of your payment depends on day you were born, as follows:

- ◆ If your date of birth was from the 1st to the 10th, your benefits will be paid on the second Wednesday of the

month

- ◆ If your date of birth was from the 11th to the 20th, your benefits will be paid on the third Wednesday of the month
- ◆ If your date of birth was from the 21st to the 31st, your benefits will be paid on the fourth Wednesday of the month

The easiest way to receive your benefits is electronically via direct deposit to your bank. You can also have them automatically deposited into your Direct Express® Debit MasterCard® account. You can sign up for direct deposit either through your own bank or through the Social Security Administration....[Read More](#)

Are Social Security disability payments for lifetime?

While Supplementary Security Income (SSI) is distributed to the majority of Americans once they retire. It is distributed to those who have little to no retirement savings. In contrast, the Social Security Administration (SSA) distributes its flagship disability support, known as Social Security Disability Insurance (SSDI), to anyone who requests it, with some caveats.

Before applying for disability benefits, you have to prove to the SSA that your disability fits their criteria of one that prevents you from working. Furthermore, the **claimant must also have been disabled for at least five full months**. The only exception is for claimants with amyotrophic lateral sclerosis (ALS) whose benefits can start

immediately.

While there are hurdles to pass in beginning the benefits regime, as long as your disability persists you are not going to be removed as a recipient.

How long can payments continue?

Disability **benefits will continue as long as your medical condition has not improved and this prevents you from working**. Benefits won't necessarily continue indefinitely, the SSA will review your case periodically to make sure you still have a qualifying disability. If it is determined that you are fit to work then the disability benefits will end and you will be classed as unemployed.



Moreover, **you need to tell the SSA if any of the following occur:**

- ◆ There's any change in your ability to work.
 - ◆ You return to work.
 - ◆ Your medical condition improves.
- If your situation has changed in these regards and the SSA is not notified then that **could potentially amount to fraud**.
- If the beneficiary dies while receiving Social Security benefits, then the check that is received the following month must be returned to the SSA.
- How do disability payments interact with normal social security benefits?
- The payments for SSI benefits are set by the federal government but can be contributed to by

individual state governments. **If a beneficiary receives SSDI benefits that will be included in what Social Security calls your "countable" income**. The amount that exceeds that federally set threshold will be subtracted from the monthly payment a recipient is entitled to, **minus a \$20 exemption**. Both the "countable" income and **maximum federal SSI payment** are set at **\$841 a month for individuals and \$1,261 for couples in 2022**. The **average SSDI benefit** for a disabled American was **about \$1,358.30 a month** throughout 2021. The majority of beneficiaries receive modest payments, **85 percent get less than \$2,000 a month as of December 2021**.

FDA officials say annual Covid-19 shots may be needed in the future

The United States might need to update its Covid-19 vaccines each year, according to a trio of top US Food and Drug Administration officials, and "a new normal" may include an annual Covid-19 vaccine alongside a seasonal flu shot.

"Widespread vaccine- and infection-induced immunity, combined with the availability of effective therapeutics, could blunt the effects of future outbreaks. Nonetheless, it is time

to accept that the presence of SARS-CoV-2, the virus that causes COVID-19, is the new normal. It will likely circulate globally for the foreseeable future, taking its place alongside other common respiratory viruses such as influenza. And it likely will require similar annual consideration for vaccine composition updates," Dr. Peter Marks, director of the FDA's Center for Biologics Evaluation



and Research; Principal Deputy Commissioner Dr. Janet Woodcock; and new FDA Commissioner Dr. Robert Califf wrote in a paper published in the medical journal JAMA on Monday.

"During the 2022-2023 COVID-19 vaccine planning and selection process, it is important to recognize that the fall season will present a major opportunity to improve COVID-19 vaccination coverage with the

goal of minimizing future societal disruption and saving lives," they wrote. "With the plan for implementation of this year's vaccine selection process, society is moving toward a new normal that may well include annual COVID-19 vaccination alongside seasonal influenza vaccination.

[Read More](#)

RI ARA HealthLink Wellness News

Doctors Devise Safer Alternative to Opioids During, After Surgeries

It's been slightly more than a year since Jonathan Akinrele, 23, underwent **weight-loss surgery**, and so far, so good.

He is now down 130 pounds, and he was able to get through gastric sleeve surgery and recovery without taking any opioids for pain.

"The pain right after surgery was more like a stomach ache. It was a little uncomfortable, but completely manageable," said Akinrele, who manages a security firm in Long Island, N.Y.

There is a big push across all of medicine to find alternatives to opioids due to the nationwide **opioid epidemic**. Many people first become

addicted to these powerful painkillers following surgery.

And the risk for addiction may be even higher for people who undergo weight-loss surgery. This is why guidelines from **five medical societies**, including the American Society for Metabolic and Bariatric Surgery, call for opioid-free or opioid-sparing pain relief during and after weight-loss surgery.

About 3% to 4% of people who receive opioids for the first time after surgery are still taking them a year later, and this jumps to 8% to 10% for people who had weight-loss surgery, said Dr. Dominick Gadaleta, chair of surgery at South Shore



University Hospital in Bay Shore, N.Y.

Better pain relief

Instead of opioids, people undergoing weight-loss surgeries at Northwell Health Hospitals in New York receive **intravenous acetaminophen** or nonsteroidal anti-inflammatory drugs (**NSAIDs**) before surgery. This is followed by an intravenous infusion of **non-opioid anesthetics** and a nerve block of the surgical area. So far, surgeons at Northwell hospitals have performed more than 200 procedures using this protocol, including gastric sleeve surgery and hernia operations.

"We essentially turn the nerve

endings down or off before surgery with preemptive acetaminophen or NSAIDs," explained Dr. Don Decrosta, chair of anesthesia at South Shore University Hospital, which is part of the Northwell health system. "When we get hurt or undergo surgery, the nerve endings in the injured area fire at a much higher rate, but if we blunt or eliminate this stress response with preemptive [pain relief], you get through the early healing days without the need for opioids."

Opioids block pain signals between your brain and body, while the new protocol is more targeted, he said,...**Read More**

Uncontrolled Blood Pressure, Diabetes May Be Common Among People With Heart Failure

Many people with heart failure also have diabetes or high blood pressure. But new research suggests those conditions, even when treated, aren't well controlled, placing people at risk for worsening heart problems.

"We know that controlling hypertension and diabetes is critical for people with heart failure," said Dr. Madeline Sterling, a primary care physician at Weill Cornell Medicine in New York City. "But few studies have been able to ascertain how well those risk factors have been controlled. This study really takes a big step

forward in doing that."

Sterling wrote an editorial accompanying the study that appeared Thursday in the American Heart Association's journal *Circulation: Heart Failure*.

Heart failure occurs when the heart can't pump as well as it should and fails to deliver enough oxygen to the body, making it harder for people to perform everyday tasks. Hypertension, another name for high blood pressure, and diabetes are major risk factors for heart failure, which affects more than 6 million people in the U.S.,



especially those who have other heart problems or who have had heart attacks.

In the new study, researchers analyzed 18 years of data from the National Health and Nutrition Examination Survey, a series of federal studies assessing the prevalence of major diseases and their risk factors among U.S. adults.

While just 8% of 1,423 people diagnosed with heart failure had poor glycemic control, defined in the study as a hemoglobin A1C level of 8% or higher, 21% of those being treated for diabetes

failed to meet blood glucose goals. This did not vary by race or ethnicity.

Researchers also found 48% of people with heart failure had uncontrolled hypertension, which the researchers defined as a systolic blood pressure, the top number in a reading, of at least 130. Among people prescribed blood pressure-lowering medication, poor control was even higher, at 51%. Black adults had higher uncontrolled rates than their white peers, at 53% compared to 47%....**Read More**

Thinking of Donating a Kidney? New Data Shows It's Safe

If you're thinking about donating a kidney, new research could alleviate your concerns.

"The results of this study are extremely reassuring for individuals who are considering being living kidney donors. We found that this lifesaving surgery, when performed at experienced transplant centers, is extremely safe," said study co-author Dr. Timucin Taner, chair of transplant surgery at Mayo Clinic's Center for Transplantation and Clinical Regeneration in Rochester, Minn.

The study included more than 3,000 living kidney donors who underwent **laparoscopic surgery** to remove the donated organ from 2000 to 2019. They were followed for up to 120 days after surgery.

All of the kidney removal procedures were performed at the transplantation center.

Overall, about 12% of the patients had postsurgical complications, most involving an infection or **hernia** related to the incision. About three-quarters of the complications occurred after



patients left the transplant center, and most of the complications occurred in the earlier years of the study.

Only 2.5% of patients had major complications, and all of them had complete recoveries. None of the living donors died, according to the study.

The results were published April 25 online in the journal **Mayo Clinic Proceedings**.

"While this study reinforces the safety of this surgical procedure, it does highlight the

importance of following up with the donors after donation. That ensures any complications can be treated quickly without any long-term damage," Taner said in a clinic news release.

Nearly 90,000 people in the United States are waiting for a kidney transplant. Recipients who receive a kidney from a living donor generally have better outcomes. Living donor kidneys usually function longer than those from deceased donors, according to the Mayo Clinic.

Race, Income Can Be Roadblocks to Recovery From Depression

If you're battling depression, the success of your treatment might be affected by your race, income, job status and education, a new study says.

"If you're going home to a wealthy neighborhood with highly educated parents or spouse, then you're arguably in a much better environment for the treatment to be effective than if you're going to a poor neighborhood with other problems," said study co-leader Jeffrey Mills, a professor of economics at the University of Cincinnati. He spoke in a university news release.

Mills and his colleagues said their findings could prove valuable in clinical trials and for doctors trying to help people

with depression. For **the study**, they looked at 665 patients who had equal access to **depression treatment**.

After controlling for sex, age and treatment type after 12 weeks of antidepressant medication, the researchers found that non-white patients had 11.3% less improvement in their depression compared to white patients.

But **economic factors** and education were important, too.

Unemployed patients had 6.6% less improvement than those with jobs; those with incomes in the bottom quarter had 4.8% less improvement than those with incomes in the top quarter, and those without a



college degree had 9.6% less improvement than college graduates.

Patients who were non-white and unemployed, didn't have a college degree and had incomes in the bottom quarter had 26% less improvement than those who were white and had jobs, a degree and income in the highest quarter, according to the study.

The findings were published recently in the journal **Psychiatric Services**.

The researchers said the study shows the importance of considering a patient's personal situation when analyzing the effectiveness of depression treatment.

Along with providing helpful

information for doctors treating patients with depression, the findings could improve clinical trials of depression therapies by highlighting the need to pay more attention to **socioeconomic variables**, according to study co-leader Dr. Jeffrey Strawn, a professor of psychiatry and behavioral neuroscience at the University of Cincinnati.

"When we don't control for these variables, which we often do not in our clinical trials because of differences in populations, we may miss detecting an effective treatment because its effect is obscured," Strawn said in the release. "So it can potentially jeopardize our treatment development by not accounting for these factors."

To stave off dementia, change up your diet

There's plenty of talk about foods that can improve brain function. Amelia Nierenberg reports for the **New York Times** on "brain food," along with its effect on your mental health and how you think. To stave off dementia, you might consider changing up your diet.

We don't yet know as much as we'd like about the causes of **dementia**. But, we do know that loss of mental acuity is more common among people with heart disease and high blood pressure, people who are

overweight and people with diabetes. And, people who don't eat well and don't exercise are more likely to have these conditions and experience dementia.

We also know that people who eat more fresh foods, nuts, fruits, vegetables, as well as whole grains and olive oil are likely to have greater protection against developing dementia. Fatty fish rich in omega-3 fatty acids are particularly great for the brain, as are blueberries, walnuts,



lentils, soybeans and leafy greens.

One recent study found that people who largely ate these foods and not processed foods or red meat, people who followed the **Mediterranean and MIND diets**, are far less likely (by 30-35 percent) to suffer from a mental impairment than people who do not.

If you're keeping your arteries in good order, you are more likely to be keeping your brain in good order as well. Eating a

variety of different-colored foods and foods packed with **flavonoids** matters.

Vitamin supplements are of little or no help in preventing against mental decline. Supplements are no substitute for a Mediterranean or MIND diet. And, many supplements contain **harmful ingredients**.

Words of wisdom from a Mayo clinic physician: "If it comes from a plant, eat it. If it's made in a plant, don't eat it."

Patients Hospitalized With COVID Face Similar Risks, Regardless of Variant

If you're unlucky enough to need hospitalization for COVID-19, it won't really matter which variant you're infected with: The same level of care is required for patients with either Delta or Omicron, a new study reveals. This is true even though people infected with the **Omicron** variant of COVID-19 are much less likely to be hospitalized than those with the **Delta** variant, the study authors said.

"It's true that patients with Omicron were significantly less likely to be admitted to the hospital than patients with Delta. But Omicron patients who did need hospitalization faced a risk of severe disease comparable to those hospitalized with Delta,"

said lead study author Heba Mostafa. She is an assistant professor of pathology at Johns Hopkins University School of Medicine, in Baltimore.

"For many people, it is not a mild infection at all," Mostafa added.

For the study, the investigators analyzed specimens from more than 2,000 patients who tested positive for **COVID-19** in order to identify whether they had Delta or Omicron, and to determine their viral load — the amount of virus in the body.

The researchers also compared the patients' outcomes, and found that only 3% of those with



Omicron were hospitalized, compared with nearly 14% of those with Delta.

But among hospitalized patients, about 68% of those with Omicron and 73% of those with Delta required supplemental oxygen. Almost 18% of those with Omicron and about 25% of those with Delta were admitted to intensive care, the study authors reported.

There were no significant differences in viral loads between patients with Omicron and those with Delta, regardless of vaccination status, according to the report published in the May issue of the journal **eBioMedicine**.

"It is a common belief that the

Omicron variant is less severe than previous variants," Mostafa said in a Hopkins news release. "We wanted to put that to the test and see whether clinical outcomes and viral loads actually differed between Delta and Omicron infections."

The findings show the need to take Omicron and future variants seriously, she added.

The patients in the study tested positive for COVID between the last week of November 2021 and the end of December 2021. By the end of this period, Omicron had replaced Delta as the dominant variant.

At US Hospitals, a Drug Mix-Up Is Just a Few Keystrokes Away

More than four years ago, Tennessee nurse RaDonna Vaught typed two letters into a hospital's computerized medication cabinet, selected the wrong drug from the search results, and gave a patient a fatal dose.

Vaught was prosecuted this year in an **extremely rare criminal trial for a medical mistake**, but the drug mix-up at the center of her case is anything but rare. Computerized cabinets have become nearly ubiquitous in modern health care, and the technological vulnerability that

made Vaught's error possible persists in many U.S. hospitals.

Since Vaught's arrest in 2019, there have been at least seven other incidents of hospital staffers searching medication cabinets with three or fewer letters and then administering or nearly administering the wrong drug, according to a KHN review of reports provided by the **Institute for Safe Medication Practices**, or ISMP. Hospitals are not required to report most drug mix-ups, so the seven incidents are undoubtedly



a small sampling of a much larger total.

Safety advocates say errors like these could be prevented by requiring nurses to type in at least five letters of a drug's name when searching hospital cabinets. The two biggest cabinet companies, Omnicell and BD, agreed to update their machines in line with these recommendations, but the only safeguard that has taken effect so far is turned off by default.

"One letter, two letters, or three letters is just not enough,"

said Michael Cohen, the president emeritus of ISMP, a nonprofit that collects error reports directly from medical professionals.

"For example, [if you type] M-E-T. Is that metronidazole? Or metformin?" Cohen added. "One is an antibiotic. The other is a drug for diabetes. That's a pretty big mix-up. But when you see M-E-T on the screen, it's easy to select the wrong drug."...**Read More**

Could Asthma Treatment Raise Your Odds for Obesity?

Adults who suffer from **asthma** often need to take corticosteroids to open up their airways, but the medications may have an unintended side effect: New research shows the treatment, particularly when taken in pill form, raised the risk of patients becoming obese.

"**Oral corticosteroids** are often given to asthma patients, particularly those who had a long history of asthma, and oral corticosteroids were found to have a direct effect on the development of obesity among those asthmatic people," said lead researcher Subhabrata Moitra. He is a postdoctoral fellow at the University of Alberta in Edmonton, Canada.

Moitra noted that patients using inhaled corticosteroids weren't at increased risk for obesity.

"Often oral corticosteroids are prescribed indiscriminately without looking for other alternatives," he said. "That's

one of the major reasons that oral corticosteroids were a very important risk factor for the development of **obesity**."

Doctors have many alternatives to oral corticosteroids to control asthma, Moitra said, including inhaled corticosteroids and the new **biologics**.

Patients who know what triggers their asthma can also avoid those triggers. Some triggers can be related to work or exposure to air pollution or tobacco smoke, he said.

Using data from the European Community Respiratory Health Survey between 1990 and 2014 and with follow-ups approximately every 10 years on more than 8,700 people, Moitra's team found that about 15% of those without asthma became obese, compared with nearly 17% of those with asthma. After accounting for factors such as asthma and



smoking, those with asthma had a 21% greater risk for obesity than those without asthma, the researchers found.

People who had asthma the longest had a 32% higher risk of becoming obese than those who had asthma for the shortest time. For people using oral corticosteroids, the risk for obesity was 99% higher when compared with those not using these medications. These risks were similar among both women and men, the researchers found.

Once someone has become obese, stopping oral corticosteroids won't automatically result in lost weight. Also, obesity makes asthma harder to control, Moitra said.

"Even if you stop taking steroids but don't change your lifestyle, or do physical activity, or change your diet, I don't think that is going to impact obesity," he said. "Obesity further

exacerbates the asthma, then you need a steroid or more other medication to control your symptoms. So it's actually a feedback loop."

The report was published online April 27 in the journal **Thorax**.

One expert doesn't think that oral corticosteroids completely explain why adults with asthma are prone to obesity.

"The association between obesity and asthma has been well-established, in that obesity not only increases the risk of developing asthma but also increases the severity, makes asthma harder to control and decreases the effectiveness of standard medications," said Dr. Sherry Farzan, an allergy and immunology physician at Northwell Health in Great Neck, N.Y....**Read More**

Nursing shortage? Robots can help

John Leland reports for the **New York Times** on robots designed to help meet the needs of nursing home residents. With a nursing shortage, nursing homes are often understaffed. Robots can help provide physical and emotional support, "virtual assisted living."

The robots are designed to meet a whole range of needs and look like a miniature person, standing four feet tall. They have eyes and mouths, hands

and legs. They also have an iPad affixed to their chests.

One key role a robot plays in a nursing home is companionship. The pandemic has brought with it massive nursing shortages. Reports indicate that more than 400,000 people who had worked at long-term care facilities no longer do. Among other things, this mass worker exodus has left many nursing home residents feeling



completely isolated. **What can robots do in addition to keeping people company?** They can offer reminders to take medicines, call for help if someone needs it, teach yoga and tai chi. New technologies are enabling robots to tell jokes, sing songs, play games, and kill germs in a room using ultraviolet lights.

Technical glitches remain. As of now, they might fall while

demonstrating a yoga or tai chi pose and might not be able to pick themselves up. Before too long, robots will be able to help people recall good memories, be it their wedding or the birth of a child.

What if robots are not your thing or otherwise not available to you? The number of **low-cost devices** that can monitor just about everything you do and help you in all kinds of ways is soaring.

More Than Annoying: Men's Urinary Issues Tied to Shorter Lives

Urinary incontinence can plague men as they age, but a new study suggests it may be more than just a bothersome condition and might actually be a harbinger of early death.

"This indicates the importance of assessing the general health, risk factors and **major comorbidities** among men with LUTS [lower urinary tract symptoms]," wrote the researchers, who were led by Jonne Akerla from the department of urology at Tampere University Hospital in Finland.

The team analyzed LUTS in more than 3,000 Finnish men who had enrolled in a study in 1994, when they were 50, 60 or 70. The research included a 24-year follow-up in 2018 of 1,167 of the men. About half had died during the intervening years.

The team looked at the men's lower urinary tract symptoms as a risk factor for death, adjusting for age and other medical conditions and considering whether the symptoms "bothered" the men.

In general, moderate and



severe lower urinary tract symptoms were markers of poor health, according to the team.

Dr. Craig Comiter, a professor of urology at Stanford University School of Medicine in California, found the study intriguing, as prior studies have not shown a link between mortality and incontinence.

"The authors are to be lauded for their measured conclusions, hypothesizing that urinary symptoms are more of a marker of poor health than a direct cause of death," Comiter said. He

described LUTS as any disorder that affects urinary storage, including excess urine production, incomplete bladder emptying, neurologic and myogenic (muscular) disorders of the bladder and **benign prostate obstruction**.

These urinary dysfunctions can be caused by a variety of common medical conditions, including heart disease or neurological conditions, diabetes, sleep disorder, restricted mobility, Parkinson's disease, dementia, stroke and multiple sclerosis....[Read More](#)

Black Patients Less Likely to Get High-Tech Prostate Cancer Therapy

(HealthDay News) -- Use of a high-tech radiation cancer treatment called **proton beam therapy** (PBT) has increased overall in the United States, but Black patients are getting it less often than white patients, two new studies show.

Traditional radiation treatment is photon-based, but PBT uses protons to deliver high-energy beams more precisely to tumors and **reduce damage to surrounding healthy tissue**.

PBT can be better than traditional radiation therapy for tumors with complex anatomy, tumors surrounded by sensitive tissues and childhood cancers, but PBT can be twice as expensive, according to the American Cancer

Society.

To assess the use of PBT in the United States, researchers analyzed data on nearly 6 million patients in the National Cancer Database. They found that overall use of PBT for newly diagnosed cancers rose from 0.4% in 2004 to 1.2% in 2018.

Private coverage was the most common type of insurance among patients treated with PBT for recommended cancers, while Medicare was the most common insurance among patients treated with PBT for cancers for which the treatment's efficacy is still under investigation.

The study also found that Black patients were less likely to be



treated with PBT than white patients (0.3% vs. 0.5%), especially for cancers for which PBT is recommended over traditional radiation therapy.

In fact, this racial disparity widened as the number of facilities offering PBT increased, and the disparity did not disappear after the researchers accounted for socioeconomic status or type of health insurance.

The studies were published in the journal **JAMA Network Open**.

"We found that PBT use increased nationally between 2004 and 2018 for all eligible cancers, especially for cancers for which PBT is the recommended radiation treatment," said Leticia

Nogueira, lead author of both studies. She is a senior principal scientist, health services research, at the American Cancer Society.

"Especially concerning, however, was our findings also showed racial disparities increased as availability of PBT increased in the U.S.," Nogueira said in a society news release.

"Our findings, unfortunately, highlight the fact that Black patients continue to benefit less from advances in medicine like PBT, even with increased availability of recommended treatment modalities," Nogueira said. "Efforts other than increasing the number of facilities that provide PBT will be needed to eliminate these disparities."

Alzheimer's Research Casts Doubt on Safety of Popular Brain Supplements

A dietary supplement believed to protect against **Alzheimer's disease** might instead be potentially harmful to the brain, a new study warns.

L-serine is an amino acid that serves many different roles in the body, and one is to influence the development and function of synapses in the brain.

Clinical trials are underway to test serine supplements in older adults experiencing cognitive decline, researchers said, based on the thought that a lack of serine might fuel development of dementia and Alzheimer's disease.

But new findings suggest the opposite is true -- elevated serine levels might instead contribute to Alzheimer's disease, researchers

reported May 3 in the journal *Cell Metabolism*.

"We are trying to say, be cautious," said lead researcher Xu Chen, an Alzheimer's disease researcher and assistant professor of neuroscience at the University of California, San Diego. "If you're trying to prevent Alzheimer's disease or cognitive decline during aging, serine might not help you and, in fact, might be doing something bad."

This scientific controversy revolves around an enzyme called **PHGDH**, which is a key ingredient for production of serine in the brain.

A *Cell Metabolism* study published in 2020 had argued that PHGDH



levels are lower in the brains of Alzheimer's patients, and suggested that L-serine tablets could be a "ready-to-use" therapy for Alzheimer's, the new report's authors said in background notes.

"You can buy it on Amazon," Chen said of L-serine. "The rationale behind it is simple. They're saying it supports your brain function, because it's one of the components of your neuronal receptors."

However, research by Chen and her colleagues revealed that there's actually a steep increase in PHGDH among Alzheimer's patients, as well as in healthy people approximately two years before they were diagnosed with the disease.

Chen's team analyzed genetic samples taken post-mortem from the brains of people in four different research groups, each made up of 40 to 50 people ages 50 and older. The subjects consisted of Alzheimer's patients, people without cognitive problems whose brains showed early signs of Alzheimer's-related changes, and folks with healthy brains.

The researchers found a consistent increase in PHGDH among both Alzheimer's patients and people with early signs of Alzheimer's, compared to the healthy control group....[Read More](#)