Biden Administration to Require Prior Authorizations for Urgent Care Within 72 Hours

The Centers for Medicare & Medicaid Services have unveiled a new rule intended to speed up health insurance company decisions on whether to authorize medical care or treatments for millions of patients. The rule requires insurers to tell doctors and patients whether the cost for an urgent medical service will be covered within 72-hours.

Prior authorizations are a standard health insurance practice that places administrative burdens and delays on both patients and doctors. The authorization process requires health insurers to vet requests before health professionals can proceed with billing for important services.

The new rule – which will go into effect in 2026 for Medicare, Medicaid, and Affordable Care Act insurance plans – also requires health insurers to provide a reason if they deny a request for a procedure or treatment. This stipulation will ease the appeal process, giving patients a detailed path for traction during the Trump Administration. The rules seek to require some low-income adults to work, attend school or volunteer as a condition of health care coverage.

Critics of Medicaid work requirements point out that most adults with Medicaid already work, and that the requirements create barriers that prevent eligible people from getting insurance coverage. More than 3 in 5 nondisabled, working-age adults enrolled in Medicaid worked in 2021, while another 20% reported not working because they were caregivers or were in school, according to KFF.

During the Trump administration, 13 states received approval for Medicaid work requirements, and several others sought permission. Some of those approvals were struck down by courts on procedural grounds. Georgia is currently the only state with a Medicaid work requirement, after a federal judge allowed a Trump-approved waiver to move forward.

“Medicaid work requirements would lead to more than a million people losing the health care they need,” said Richard Fiesta, Executive Director of the Alliance. “We must create an economy with good paying jobs and make health care affordable for all.”

NOTE: Total may not sum to 100% due to rounding.

Work Status & Barriers to Work Among Medicaid Adults, 2021

Executive Director of the Alliance. “We must create an economy with good paying jobs and make health care affordable for all.”

NOTE: Total may not sum to 100% due to rounding.

Working Full-Time is based on total number of hours worked per week (at least 35 hours). Full-time workers may be simultaneously working more than one job. SOURCE: KFF analysis of March 2022 Current Population Survey.

Union Membership Grew by 139,000 in 2023 in a Win for Workers, Retirees

On Tuesday the U.S. Bureau of Labor Statistics released its annual report on union density. Union membership in the private sector increased by 191,000 members, with a majority of new members under the age of 45.

“Workers are fed up with low wages, few benefits, and a lack of dignity and respect on the job, which is precisely why more are interested in joining a union now than ever before,” said AFL-CIO President Liz Shuler. “Not only are more Americans in a union, but 900,000 union members won double-digit wage increases through new contracts last year.”

“This report is great news for retirees and active workers alike,” added Joseph Peters, Jr., Secretary-Treasurer of the Alliance. “When active workers have union jobs that come with higher wages, superior health care benefits and pensions, their retirements are also much more secure.”
Are lower income individuals enrolling in Medicare Advantage for the wrong reasons, at their peril?

Medicare Advantage enrollment is up, and people with low incomes and people of color are enrolling in Medicare Advantage at disproportionate rates. A new study published in JAMA by Avni Gupta, BDS, MPH, Diana Silver, PhD, David J. Meyers, PhD; et al. finds that lower income individuals are often drawn into Medicare Advantage because of ads promising vision and dental benefits. The authors consider whether this is a good reason for people to enroll in a particular plan or whether these people are more likely to end up in Medicare Advantage plans that threaten their access to care.

Many people of color and low income individuals rely on misleading marketing to make their choices, which is highly problematic.

The worst performing Medicare Advantage plans are largely responsible for tens of thousands of unnecessary deaths a year. But we don’t know which ones they are. The data is not available. People who enroll in a Medicare Advantage plan take a gamble that if they develop a serious condition they will get the care they need.

The American Hospital Association (AHA) has urged the government to step in to protect patients in Medicare Advantage. The AHA explains the harm to patients from prior authorization rules that lead to delays and denials of critical care. So does the HHS Office of the Inspector General. The Centers for Medicare and Medicaid Services, which oversees Medicare Advantage, does not have the resources to conduct adequate oversight and enforcement.

In this study, the data show that Black Americans were more likely to sign up for MA plans with dental or vision benefits than White Americans. People with incomes no more than twice the federal poverty level also were more likely than higher income individuals to enroll in Medicare Advantage plans with dental benefits.

It’s not clear from the study whether the MA plans with dental and vision benefits have better or worse health outcomes. As it is, they have on average 43 MA plans to choose from, all differing in ways that are impossible to assess, including with respect to premiums, deductibles and out-of-pocket caps, which are knowable, and with respect to typical out-of-pocket costs, denial and delay rates, and mortality rates, which are not knowable. What is clear is that people who enroll in a Medicare Advantage plan take a big gamble with their health and well-being that they will be able to get the care they need should they develop a complex and costly condition.

Vision and dental benefits in MA plans tend to come with high out-of-pocket costs and to be restricted. While data is limited, it appears that most people do not end up using these benefits, either their dental and vision needs are not covered or they can’t find a provider to see them or their costs are unaffordable.

What will happen to dental and vision benefits when the government addresses overpayments to MA plans? Based on prior research, changes to these benefits are likely to be minimal. One researcher found that with $1,000 less to spend, MA plans increased monthly premiums by $5. There is also a five percent risk that vision or hearing benefits would end.

What will happen to Medicare if the government does not address overpayments to MA plans? It is not unlikely that Traditional Medicare will wither on the vine and that insurers will take over all of Medicare. Because they cost so much and often delay and deny care inappropriately, more people with Medicare are likely to be unable to afford or get the care they need, endangering their health and well-being.

If you’re in a Medicare Advantage plan, take advantage of the Medicare Advantage Open Enrollment period, which runs through March 31. If you can, switch to Traditional Medicare if you want to ensure easy access to the care you need.

Replicants support “backroom scheme” to cut Social Security and Medicare

Jake Johnson reports for Common Dreams on the Republican push in Congress for a “Fiscal Commission” and the Democratic pushback against it. Senate Finance Committee Chair Ron Wyden correctly calls the proposed Commission a “backroom scheme” to cut Medicare and Social Security.

The House Budget Committee’s Fiscal Commission Act, which Republicans intend to link to a must-pass government funding bill, would allow Congress to cut “Americans’ earned benefits” behind closed doors, said Senator Wyden.

Senator Wyden and the overwhelming majority of Democrats oppose the Commission. Wyden’s argues that Congress should be raising taxes to strengthen Medicare and Social Security: “Instead of trying to cut Social Security, Medicare, and Medicaid, Republicans should work with Democrats to ensure the wealthy pay their fair share, which would go a long way towards securing Social Security and Medicare long into the future.” Absolutely! The question now is whether the Democrat-led Senate will allow he Fiscal Commission Act to become law. If so, the Commission, a 16-person panel, made up of members of Congress from the House and Senate and private sector influencers, would develop and vote on Medicare and Social Security policies that Congress would consider passing into law, with no amendments permitted.

It’s no secret that Republicans want to privatize both Social Security and Medicare and cut spending, leaving older adults and people with disabilities at even greater financial and health risk than they already are. Republicans have no intention of enacting legislation that would raise revenue to strengthen these programs and never have. Indeed, Republican members voted against a change to the Fiscal Commission legislation that included this language concerning the work of the Fiscal Commission: It “shall propose recommendations to strengthen and secure Social Security” by “protecting Social Security benefits” and requiring the wealthy to contribute more to the program.

Republicans also rejected the following proposed language about the role of the Fiscal Commission: It “shall propose recommendations to strengthen and secure Medicare” by “protecting the traditional Medicare program” and extending its solvency by “requiring taxpayers with incomes above $400,000 to contribute more” and closing a loophole that allows rich business owners to avoid Medicare taxes.

It’s also no secret that Trump, if reelected, stands with these Republicans in Congress. “Donald Trump can’t hide from his own words: He told the American people four years ago that he would cut Social Security and Medicare if he ever got a second term in office, and has only doubled down on his pledge to gut these critical programs since then. After proposing disastrous cuts to Social Security and Medicare in every single one of his budgets as president, Trump is still running on the same out-of-touch plans that would threaten the pocketbooks of America’s seniors,” said Alex Floyd of the DNC.

Republicans believe we spend too much money on Medicare and Social Security. But, Social Security and Medicare Part A—hospital insurance—are self-funded. And, both Medicare and Social Security offer critical supports to the most vulnerable Americans. Without them, our government will endanger the lives of millions of our parents and grandparents.
Biden administration finalizes Medicare Advantage prior authorization rule

Last week, the Biden administration finalized a prior authorization rule that, among other things, will require insurers offering Medicare Advantage plans to use an electronic prior authorization process, determine whether to approve requests more speedily, and report on their prior authorization denials. But, the rule does not take effect for three years and still leaves people with urgent health care needs at risk of not getting timely care and suffering serious harm in Medicare Advantage.

If you’re enrolled in Medicare Advantage, you should take advantage of the Medicare Advantage Open Enrollment Period, which end at the end of March, and study your Medicare options. Traditional Medicare has no prior authorization requirements and you are covered for care anywhere in the US. Traditional Medicare also has no out-of-pocket cap, so it’s good to get supplemental coverage if you don’t have Medicaid. Supplemental plans K and L are lower cost.

The Centers for Medicare and Medicaid Services’ final prior authorization rule does not dictate when or how often insurers can use prior authorization, nor does it require insurers to disclose this information. And, it still allows insurers to take a week to make a determination on a standard prior authorization request and 72 hours on an urgent request. When people urgently need care, a 72-hour wait could literally kill them in some cases.

Moreover, the new prior authorization rule doesn’t apply to prescription drug coverage. Right now, some Medicare Advantage plans require people with diabetes to go through a prior authorization process each time they need a continuous glucose monitor, even though it is standard treatment.

Given that many insurers impose prior authorization rules that are not evidenced-based and that can lead to serious harm to the most vulnerable patients, CMS should be establishing a standard set of prior authorization rules that Medicare Advantage plans can use. Standardizing prior authorization also would be a step towards helping people distinguish among Medicare Advantage plans in meaningful ways; they should know how often the MA plans will force them to go through prior authorization hoops.

Today, people choose Medicare Advantage plans with blindfolds on. The government does not allow them to meaningfully distinguish among plans, let alone protect them from plans that are bad actors. Denial rates in some MA plans are more than 25 percent, but no one knows which deny care inappropriately at high rates and which

People can’t know whether their plan will make them go through mega hoops before they can receive urgently needed care or whether their plan will inappropriately deny critically needed care. Even with these prior authorization final rules in effect, they won’t know. Insanity, I say.

What All Retirees Need to Know About Social Security in 2024

For starters, benefits are bigger in 2024. Also, the program isn’t running dry anytime soon.

If you're retired, or are planning to retire in the near future, Social Security is likely to be delivering a significant chunk of your retirement income. The program boasts nearly 50 million retired beneficiaries and also provides support to millions of disabled workers, and dependents of retirees and deceased retirees.

It's important, then, to keep up with Social Security changes and challenges over the years. Here's a look at some things to know about Social Security, as of 2024.

1. Know what you can expect from Social Security

First, if you're not yet collecting your Social Security benefits, know what you can expect from Social Security, as that can help in your retirement planning.

Know, for example, that as of November, the average monthly retirement benefit was $1,845, or about $22,000 for the year. That's a helpful sum but not enough for most folks to live on. And yes, many are receiving more than that but not that much more.

The rather unattainable maximum benefit was $4,873 per month, or about $58,500 annually.

You can get a much clearer estimate of how much you can expect to collect from Social Security by setting up a "my Social Security" account at the Social Security website. After you do that, you’ll be able to access the Social Security Administration's (SSA's) record of your earnings by year, which can allow you to spot any errors and then have them fixed.

You'll also be able to see estimates of how much you may collect in the future, depending on various factors, such as when you start collecting.

• 2. Benefits are increasing by 3.2% in 2024

You may know that Social Security benefits are increased in most years via cost-of-living adjustments -- or COLAs. For 2024, benefits are going up by 3.2%. That may seem kind of small, given recent inflation levels, but inflation does seem to be more under control lately, and a 3.2% hike is actually above average. Recent increases have been much bigger, too -- 8.7% in 2023 and 5.9% in 2022. But other than those, there hasn't been an increase greater than 3% since 2011.

There are reasonable arguments to be made that Social Security COLAs are lower than they should be, but at least they do get regular increases. That can help protect retirees from the effects of inflation, which can really shrink the purchasing power of retiree incomes. (You'll likely need more income than you think in retirement, so it's smart to start saving and investing as soon as possible.)

• 3. Some numbers have changed for 2024

Next, know that many key Social Security numbers get updated regularly -- not just COLAs. For example, there's a maximum earnings limit that reflects the maximum amount of your earnings that will get taxed for Social Security. For 2023, that limit was $160,200, up considerably from 2022's $147,000. For 2024, that earnings cap is rising to $168,600. So if you're a high earner, more of your income will get taxed for Social Security. And if you're a very high earner, only a portion of your income will get taxed, while those earning $168,600 or less will see every dollar of earnings taxed.

A minor change is that the "credits" that we earn to qualify for Social Security are also increasing -- to earn one credit, the amount of earnings needed will rise from $1,640 to $1,730. To be eligible for benefits, we need to earn a total of 40 credits, and we can earn up to four per year. So for most workers, it will be fairly easy to qualify over a decade of working because four credits at the new level amounts to only $6,920 in earnings.

4. Social Security won't run dry in 2024 -- or ever

Finally, despite what you might think from various scary headlines here and there, Social Security, while definitely facing some ominous challenges, is not going away in 2024 -- or ever, most likely. Here's the problem: Since the program began, workers have been paying into the system, and beneficiaries have been collecting from it. With many more workers than beneficiaries, the program has long run a surplus. But workers are living longer and often retiring earlier these days, so the surplus is shrinking.

The Social Security trustees' 2023 report on the health of the program notes that so come 2034, you might only receive 77% of the benefits due to you. As long as workers are paying their taxes into the system, though, there will always be some money for benefits. Remember, though, that Congress can fix this problem and strengthen Social Security in various ways, and they may well do so.
When KFF Health News published an article in August about the “prior authorization hell” Sally Nix said she went through to secure approval from her insurance company for the expensive monthly infusions she needs, we thought her story had a happy ending.

That’s because, after KFF Health News sent questions to Nix’s insurance company, Blue Cross Blue Shield of Illinois, it retroactively approved $36,000 worth of treatments she thought she owed. Even better, she also learned she would qualify for the infusions moving forward.

Good news all around — except it didn’t last for long. After all, this is the U.S. health care system, where even patients with good insurance aren’t guaranteed affordable care.

To recap: For more than a decade, Nix, of Statesville, North Carolina, has suffered from autoimmune diseases, chronic pain, and fatigue, as well as a condition called trigeminal neuralgia, which is marked by bouts of electric shock-like pain that’s so intense it’s commonly known as the “suicide disease.”

“It is a pain that sends me to my knees,” Nix said in October. “My entire family’s life is controlled by the betrayal of my body. We haven’t lived normally in 10 years.”

Late in 2022, Nix started receiving intravenous immunoglobulin infusions to treat her diseases. She started walking two miles a day with her service dog. She could picture herself celebrating, free from pain, at her daughter’s summer 2024 wedding.

“I was so hopeful,” she said. But a few months after starting those infusions, she found out that her insurance company wouldn’t cover their cost anymore. That’s when she started “raising Cain about it” on Instagram and Facebook.

You probably know someone like Sally Nix — someone with a chronic or life-threatening illness whose doctor says they need a drug, procedure, or scan, and whose insurance company has replied: No.

Prior authorization was conceived decades ago to rein in health care costs by eliminating duplicative and ineffective treatment. Not only does overtreatment waste billions of dollars every year, but doctors acknowledge it also potentially harms patients.

However, critics worry that prior authorization has now become a way for health insurance companies to save money, sometimes at the expense of patients’ lives. KFF Health News has heard from hundreds of people in the past year relating their prior authorization horror stories. When we first met Nix, she was battling her insurance company to regain authorization for her infusions. She’d been forced to pause her treatments, unable to afford $13,000 out-of-pocket for each infusion.

Finally, it seemed like months of her hard work had paid off. In July, Nix was told by staff at both her doctor’s office and her hospital that Blue Cross Blue Shield of Illinois would allow her to restart treatment. Her balance was marked “paid” and disappeared from the insurer’s online portal.

But the day after the KFF Health News story was published, Nix said, she learned the message had changed. After restarting treatment, she received a letter from the insurer saying her diagnoses didn’t actually qualify her for the infusions. It felt like health insurance whiplash.

“They’re robbing me of my life,” she said. “They’re robbing me of so much, all because of profit.”... Read More

How Medicare and Social Security Affect HSA Eligibility

Those 65 and older who want to contribute to a health savings account must plan ahead.

Although numerous tax-advantaged vehicles are available for retirement savings, health savings accounts, or HSAs, have particular benefits for individuals saving for retirement.

Specifically, HSAs offer a “triple tax benefit” that includes tax-deductible contributions, tax-deferred growth, and tax-free withdrawals for qualified medical expenses. This can allow individuals to save a significant amount that can be withdrawn tax-free for medical expenses later in retirement. Therefore, for workers looking to boost their savings toward the end of their working years, HSA contributions can be the most tax-efficient vehicle available.

The caveat, however, is that to be eligible to contribute to an HSA, an individual must be covered by a qualifying high-deductible health plan, or HDHP, with no other non-HDHP coverage. And because government-funded health insurance options such as Medicare are not considered qualifying HDHP coverage, enrolling in Medicare—either directly through its website or by applying for Social Security benefits (which automatically enrolls someone in Medicare once they reach age 65)—means that an individual will no longer be eligible to contribute to an HSA.

For retirees, self-employed workers, and others who rely on Medicare as their sole option for health insurance after reaching age 65, this means there is effectively no way to contribute to an HSA after age 65. However, people who continue working beyond age 65 (or whose spouse continues working) and have access to an employer-provided HDHP can continue making HSA contributions as long as they don’t enroll in Medicare or apply for Social Security benefits. And because there’s no age cap on HSA contributions, it’s possible to keep contributing for as long as the person is still working and remains on a qualifying HDHP (although retiring and subsequently enrolling in Medicare will ultimately end HSA eligibility).

Advisors can help their clients who want to keep contributing to HSAs after age 65 by planning strategies that help to preserve their eligibility and maximize the amount they can contribute. For instance, if someone has applied for Social Security benefits and inadvertently enrolled in Medicare (which would make them ineligible for HSA contributions), they may be able to withdraw their Social Security application within 12 months and cancel their Medicare coverage to restore their eligibility—although doing so would require paying back any Social Security benefits received.... Read More

Will All Seniors Eventually Have No Choice but Medicare Advantage?

MedPAC chair discusses need to fix MA’s confusing limitations, upcoding, and rising costs
Michael Chernew, PhD, chairs the influential Medicare Payment Advisory Commission (MedPAC), an independent 17-member panel appointed by the

U.S. Comptroller General to advise Congress on Medicare policy.

MedPage Today recently interviewed Chernew by phone and email about growing concerns -- throughout the country and among commission members -- that private Medicare Advantage plans in some ways may be failing their mission to improve access to quality care and lower costs.

These plans have become the dominant way beneficiaries receive health benefits.

Chernew, who is also a health policy professor and researcher at Harvard Medical School, said he was speaking from that role.

…..Read the interview has been edited for clarity and brevity.

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Lewis Morgenstern has made up his mind. When he turns 65 in four years, he’s going to sign an advance directive for driving.

The directive will say that when his children want him to stop getting behind the wheel, Morgenstern will follow their advice.

“I recognize that I might not be able to make the best decision about driving at a certain point, and I want to make it clear I trust my children to take over that responsibility,” said Morgenstern, a professor of neurology, neurosurgery, and emergency medicine at the University of Michigan.

His wife, 59, intends to sign a similar document at 65.

Morgenstern has given a lot of thought to the often-divisive issue of when to stop driving. He co-authored a recent article in the Journal of the American Geriatrics Society that found 61% of older adults with cognitive impairment continued to drive even though 36% of their caregivers were concerned about their performance.

Many of these seniors probably adapted by exercising caution and drawing on extensive experience behind the wheel, Morgenstern said. But, he noted, “there is undoubtedly a group of people who are driving and shouldn’t be because they’re a risk to themselves and to others.”

Relatively few studies have looked at how many older adults with mild cognitive impairment or dementia continue to drive, and there aren’t any national standards on when people should hand over the car keys. But the issue is a growing concern as the ranks of seniors in their 70s, 80s, and 90s — the age group most likely to have cognitive impairment — expand.

Nearly 50 million people 65 and older held driver’s licenses in 2021, a 38% increase from 2012, according to data compiled by the American Automobile Association. Almost 19 million were 75 or older, a rise of 31%. During this period, motor vehicle deaths for people 65 and older increased 34%, reaching 7,489 in 2021. The number of seniors injured in vehicle crashes that year exceeded 266,000.

For the most part, older adults drive safely. They use seat belts more often, are intoxicated less often, and are less likely to speed than younger adults. Compared with younger and middle-aged adults, they’re involved in fewer fatal car crashes each year. And they’re more likely to restrict where and when they drive — following familiar routes, avoiding heavily trafficked streets, and not driving at night.

Still, risks for older drivers rise with advancing age and the onset of medical conditions such as arthritis, glaucoma, and Parkinson’s disease. And when crashes occur, seniors are more likely to be severely injured or die because they’re more vulnerable physically.

Cognitive impairment and dementia pose especially worrisome challenges because decision-making, attention, judgment, and risk assessment are compromised in people with these conditions.

“This is a big challenge when it comes to driving, because people don’t react appropriately and self-regulate,” said Emmy Betz, a professor of emergency medicine at the University of Colorado School of Medicine who has studied advance driving directives.

This was the case for Morgenstern’s beloved father-in-law, who developed moderate Alzheimer’s disease in his 70s but remained convinced he was fit to drive. After he got badly lost one day, Morgenstern’s mother-in-law took away the car keys, and “he didn’t understand why. He was very unhappy,” Morgenstern said.

Morgenstern’s interest in advance directives for driving, an option he recommends in his paper, springs from this experience.

Several types of directives exist. One asks a person to name a family member or friend who will talk to them about whether it’s safe to continue driving. AAA and the American Occupational Therapy Association have endorsed a directive of this kind, which is not legally binding.

Obligations also run in the other direction, with family members agreeing to help the person explore ways to keep driving, if possible. If not, family members agree to help the person find other ways to get out and about by offering rides and helping them use public transportation, carpooling services, or volunteer-driver programs. Uber and Lyft, which have created programs for seniors, are newer options frequently used. ...Read More

Preparation to Hang Up the Car Keys as We Age

In the year and a half since its launch, 988 — the country’s easy-to-remember, three-digit suicide and crisis hotline — has received about 8.1 million calls, texts, and chats. While much attention has been focused on who is reaching out and whether the shortened number has accomplished its goal of making services more accessible to people in emotional distress, curiosity is growing about the people taking those calls.

An estimated 10,000 to 11,000 counselors work at more than 200 call centers nationwide, fielding calls from people experiencing anxiety, depression, or suicidal thoughts.

A newly released report, based on responses from 47 crisis counselors, explored variations in their training and work experiences. The survey “is not large enough to support conclusions” about all 988 staffers, said Dan Fichter, the report’s author and a former program manager for the Substance Abuse and Mental Health Services Administration’s 988 team. Still, the first-of-its-kind survey — published by CrisisCrowd, a new noncommercial project focused on raising the voices of 988’s workforce — surfaced interesting snapshots.

For instance, counselors who responded noted wide variations in training, from four days or less to two weeks.

“We know that there are significant workforce challenges for 988 including staffing shortages and burnout, like much of the health care industry is experiencing today,” Monica Johnson, director of SAMHSA’s 988 & Behavioral Health Crisis Coordinating Office, wrote in a statement. “Ensuring that 988 crisis counselors are properly trained and supported to do this life-saving work is critical.”

Different training approaches emerged as one of the report’s central themes. Most counselors who responded said they were trained in four weeks or less and didn’t consider it adequate.

“I understand that even with about 120 hours of training, we can’t get through all the nuances that boost confidence,” said one anonymous survey response.

Some counselors said they had received training only in talking to people experiencing suicidal thoughts and not how to deal with other mental health issues, such as anxiety attacks, substance intoxication and withdrawal, and mood disorders. They said they had not been prepared for the wide range of calls of varying levels of intensity they would face.

“There could have been more emphasis on how different each convo would be,” noted one.

Some also suggested that opportunities to listen to 988 calls or sessions that used role-playing exercises to practice handling calls would have been helpful. The risks of counselors not being properly trained are high, said Eric Rafla-Yuan, a member of the California Governor’s Office of Emergency Services’ 9-8-8 Technical Advisory Board and a psychiatrist at San Diego County Psychiatric Hospital.

He said it is concerning that some callers may not “feel that they have the support that they need” when reaching out to 988, and “may not call again in the future.” The situation could possibly “cause more stress rather than support,” he added. ...Read More
The latest news suggests that Humana and other big insurers are losing shareholder value because they are spending more money on care in Medicare Advantage than anticipated. It’s hard to believe they aren’t profiting wildly when they have been running away with the store, raking in tens of billions of overpayments from the government each year. But, if they are losing value, it’s another reason why Congress should cut its losses on Medicare Advantage and either overhaul the program or end it entirely.

If insurers deliver shareholder value by spending less on care, then shareholder value is at odds with the needs of Medicare Advantage enrollees. And, if they can’t deliver shareholder value when they are massively overpaid, Medicare Advantage enrollee costs are likely to rise significantly if the government ends the overpayments. Right now, the Medicare Advantage plans are being overpaid $88 billion, according to the Medicare Payment Advisory Commission or MedPAC.

No one, including many Democrats in Congress, want to hear that Medicare Advantage is financially unsustainable and not delivering shareholder value for some insurers. After all, as one Just Care reader just wrote me, it’s the only option many people with Medicare believe they can afford. (Traditional Medicare has no out-of-pocket limit. So, unless they have Medicaid, people need supplemental coverage to protect themselves financially, and supplemental coverage can be expensive.)

What’s worse is that Medicare Advantage is not working for millions of people with costly conditions. It works best for people who do not need a lot of care, the people who once cost the government very little when they were enrolled in Traditional Medicare. When they need care, it’s a crapshoot whether their insurers will approve it and whether they will be able to afford the out-of-pocket costs.

Congress and the administration need to cut Medicare Advantage overpayments really soon if Medicare is going to be around in the future. They are unsustainable, and they are undermining Traditional Medicare. Without Traditional Medicare, the Medicare Advantage insurers will have no competitive pressure and their behavior, which already too often endangers people’s health and well-being, is likely to worsen.

Politically, many Democrats are likely to feel that their hands are tied, and they cannot support reforms to address the overpayments without a backlash from the insurers. Republicans seem happy to allow the waste in Medicare Advantage to continue, because it’s helping the corporations that support them. Only when they end the Medicare Advantage overpayments will Republicans and Democrats serve the needs of their constituents.

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Senate Probes the Cost of Assisted Living and Its Burden on American Families

A U.S. Senate committee on Thursday launched an examination of assisted living, holding its first hearing in two decades on the industry as leaders of both parties expressed concern about the high cost and mixed quality of the long-term care facilities.

The federal government has minimal oversight of assisted living, which is regulated by states, unlike skilled nursing homes. Both the Democratic and Republican leaders of the Senate Special Committee on Aging said their inquiry aimed to detail the financial practices and quality levels in the industry so that consumers would be better able to choose facilities.

Lawmakers expressed little appetite for Congress to take a more direct role in regulating the sector, such as by setting federal standards for staffing levels and how workers are trained.

Prompted by a New York Times-KFF Health News series, Sen. Bob Casey, the Pennsylvania Democrat who chairs the panel, put out a call for residents and their families to submit their bills so the panel could assess the industry’s business practices.

“I want to know more about what people are paying for assisted living and to have people tell their stories,” Casey said.

“We want to hear from you about the true cost of assisted living and understand whether families have the information — the information that they need — to make this difficult financial and health care decision for a family member and for the family.”

Sen. Mike Braun of Indiana, the ranking Republican on the committee, endorsed the inquiry while cautioning against actions that would lead to new financial burdens on the federal budget. “When you’re promoting transparency, it can bring odd partners together,” Braun said.

More than 800,000 older Americans reside in assisted living facilities, which cater to people who have dementia or trouble walking, eating, or doing other daily activities. Most residents have to pay out-of-pocket because Medicare doesn’t cover long-term care and only a fifth of facilities accept Medicaid, the federal-state insurance for people with low incomes or disabilities. The industry is quite profitable, running median operating margins around 20% and often charging residents with extensive needs $10,000 or more a month.

The national median cost of assisted living is $5,400 a year, according to a survey by the insurer Genworth.

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When Kristy Uddin, 49, went in for her annual mammogram in Washington state last year, she assumed she would not incur a bill because the test is one of the many preventive measures guaranteed to be free to patients under the 2010 Affordable Care Act. The ACA’s provision made medical and economic sense, encouraging Americans to use screening tools that could nip medical problems in the bud and keep patients healthy.

So when a bill for $236 arrived, Uddin — an occupational therapist familiar with the health care industry’s workings — complained to her insurer and the hospital. She even requested an independent review.

“I’m like, ‘Tell me why am I getting this bill?’” Uddin recalled in an interview. The unsatisfying explanation: The mammogram itself was covered, per the ACA’s rules, but the fee for the equipment and the facility was not.

That answer was particularly galling, she said, because, a year earlier, her “free” mammogram at the same health system had generated a bill of about $1,000 for the radiologist’s reading. Though she fought that charge (and won), this time she threw in the towel and wrote the $236 check. But then she dashed off a submission to the KFF Health News-NPR “Bill of the Month” project:

“I was really mad — it’s ridiculous,” she later recalled. “This is not how the law is supposed to work.”

The ACA’s designers might have assumed that they had spilled out with sufficient clarity that millions of Americans would no longer have to pay for certain types of preventive care, including mammograms, colonoscopies, and recommended vaccines, in addition to doctor visits to screen for disease. But the law’s authors didn’t reckon with America’s ever-creative medical billing juggernaut.
FDA Warns of Rare Secondary Cancer Risk With CAR-T Therapies

The U.S. Food and Drug Administration has told drugmakers to add a boxed warning to a type of cancer treatment called CAR-T therapy, saying the treatment itself may sometimes cause a secondary cancer.

Still, FDA spokesperson Carly Kempler told NBC News that, despite the new warning, "the overall benefits of these products continue to outweigh their potential risks."

Twenty-five reports of rare blood cancers in patients who had gotten CAR-T therapy prompted the agency to add the boxed warning, Kempler said.

CAR-T therapy uses a patient’s own immune cells to fight blood cancers such as leukemia, multiple myeloma and lymphoma. Immune cells are harvested from the patient and then genetically altered in a lab to make them target cancer cells. Once tweaked, the immune cells are infused back into the patient.

It’s a powerful therapy: In 2022, doctors who had treated two leukemia patients with CAR-T a decade ago reported that the treatment had essentially cured the patients.

“This has been a game changer when we think about treating lymphoma and other diseases,” Dr. Matthew Frigault, clinical director of the Massachusetts General Hospital Cellular Immunotherapy Program, told NBC News.

In 2017, the first CAR-T therapy, Novartis’ drug Kymriah, was approved by the FDA. Another five therapies have since been approved.

The makers of five of these drugs -- Bristol Myers Squibb, for Abecma and Breyanzi; Gilead Sciences' Kite Pharma, for Yescarta; Johnson & Johnson's Carvykti; and Novartis, for Kymriah -- must submit proposed label changes in the next 30 days to note that CAR-T therapy can raise the risk of rare blood cancers, the FDA said.

If the drugmakers disagree, they can submit a rebuttal explaining why a change isn’t needed, NBC News reported.

In a statement, a spokesperson for Novartis said the company has not found “sufficient evidence” to support a link between cancer and its treatment. However, the company will work with the FDA to update its label “appropriately,” the spokesman said.

Spokespersons for Johnson & Johnson and Gilead Sciences also told NBC News that they would work with the agency to update their labels.

A spokesperson for Bristol Myers Squibb said the company is evaluating “next steps” following the FDA's notice, although it has not seen any cancer cases associated with its treatment… Read More

Alcohol-Linked Fatty Liver Disease More Fatal for Women

Fatty liver disease can cause liver damage and can be one health effect of long-term heavy drinking.

Now, research shows that the illness can prove even more deadly for women who drink than for men.

Also called steatotic liver disease, the condition involves the steady accumulation of excess fat in the body's major blood-cleansing organ.

An impaired liver can have a major downstream effect on health, noted study lead author Dr. Susan Cheng.

“Steatotic liver disease is a major and increasingly prevalent condition that is likely an underlying precursor to many conditions, including those involving the heart,” said Cheng, who directs the Institute for Research on Healthy Aging at Cedar-Sinai’s Smidt Heart Institute in Los Angeles.

"We are paying even more attention to steatotic liver disease because we are seeing how it tracks closely with established cardiovascular risk factors such as hypertension, high cholesterol and diabetes," Cheng added in a Cedars-Sinai news release.

Not all forms of the disease are caused by excessive alcohol use, however. Two subsets of steatotic liver disease are linked to excessive drinking: Alcohol-related liver disease (ALD) and metabolic dysfunction-associated and alcohol-related liver disease (MetALD).

The new study was published in the February issue of the Journal of Hepatology.

In their research, Cheng’s group used U.S. federal government health data on over 10,000 adults. This group’s health was tracked beginning in the late 1980s and early 1990s. As part of the data, all participants underwent liver scans and other medical exams.

About a fifth of the study group developed some form of fatty liver disease over time, the researchers found, and men were twice as likely to have the condition as women.

However, over a follow-up period averaging about 27 years, women with fatty liver disease had twice the odds of dying compared to men.

When it came to the odds of dying from alcohol-related fatty liver disease, specifically, the gender gap remained.

Women with ALD had a 160% higher risk of dying than men with the condition, and they also had an 83% higher odds of dying from MetALD, Cheng’s team found…. Read More

Red Cross Repeats Call for Blood Donors as Shortage Continues

Reiterating a plea it made earlier this month, the American Red Cross is urging people to roll up their sleeves and give blood.

A series of severe winter storms this month have exacerbated an already bad situation, as a shortage of lifesaving donated blood continues, the agency said.

The storms "hampered our ability to boost critically low blood supply levels," said Red Cross spokesman Daniel Parra.

"Since the beginning of the year, blood drives have been cancelled in nearly every state where the Red Cross collects blood, causing thousands of units of blood and platelets to go uncollected," he added.

Parra explained that to bring blood supplies back up to normal levels, the agency needs to collect an extra 8,000 donations each week over the next few weeks. It's easy to find out when and where you can donate blood, by heading to RedCrossBlood.org or calling 1-800-RED CROSS (1-800-733-2767).

Already, the United States has the lowest number of people giving blood observed over the past 20 years, according to the Red Cross. When supplies are stretched thin, events such as storms can "have a huge effect on the availability of blood products," Parra noted.

"Donors in areas unaffected by severe weather are vital to ensuring those in need of transfusions have access to lifesaving care across the Red Cross network," he said.

As an added incentive, people who choose to donate during the month of January will be entered to win a trip for two to Super Bowl LVIII in Las Vegas. There's more on that at RedCrossBlood.org/SuperBowl
Drink lemonade, not alcohol, improve your health

Ian Taylor writes for BBC Science Focus Magazine about the risks of drinking any amount of alcohol. The World Health Organization (“WHO”) now advises in Lancet Public Health that no amount of alcohol is good for your health. Rather, alcohol is carcinogenic. D

In short, according to the WHO, “alcohol is a toxic, psychoactive and dependence-producing substance and [was] classified as a Group 1 carcinogen by the International Agency for Research on Cancer decades ago.” Alcohol causes liver damage, cardiac damage, cancer, and can compromise mental health. Even in small doses, it offers no benefits, as some had once believed.

The alcohol industry appreciates that alcohol is a carcinogen and does not say otherwise. The open question is whether there is an amount of alcohol one can consume that is not harmful. The answer from the International Agency for Research on Cancer appears to be no. One alcoholic drink a week increases your chances of having cancer. It also is not good for your brain. You lose grey and white matter when you drink alcohol.

Recent research shows that a small amount of alcohol has no heart benefits either. You are more likely to have hypertension and coronary artery disease if you drink alcohol.

Reducing your alcohol consumption has significant health benefits. The benefits are greater from drinking two drinks a day rather than four drinks than from not drinking instead of drinking two drinks.

If you are concerned about drinking too much alcohol, talk to your doctor. Keep in mind that Medicare covers alcohol screening and counseling.

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### No Sign Latest COVID Variant Leads to Worse Symptoms

| JN.1, the COVID variant sweeping the country this winter, is not prompting more severe disease than earlier variants did, early U.S. government data suggests. While it does not appear to be more deadly than its predecessors, the JN.1 variant has surged in recent months and now accounts for 85.7% of all U.S. cases, according to the U.S. Centers for Disease Control and Prevention. The agency is waiting for additional data to craft a more detailed analysis of JN.1’s impact this season, Dr. Eduardo Azziz-Baumgartner, chief of the global influenza branch in CDC’s Influenza Division, said during a webinar with testing laboratories hosted by the agency this week, CBS News reported. Asked if JN.1’s symptoms seemed to be more severe than earlier COVID waves, he said, "There are early signals that that may not be the case," based on electronic medical records and other data. He added that a virus' effect on an individual can vary widely, however. "It could be very severe. People could die from a virus that, to the general population, may be milder." The CDC plans to release more details about JN.1’s severity "during the next couple weeks" as more data is gathered on the variant, Azziz-Baumgartner added. Still, the CDC and other federal health agencies have not moved to deem JN.1 a variant of interest, even though the World Health Organization did just that last month. But the WHO also said last Friday that there were "currently no reported laboratory or epidemiological reports" linking JN.1 to increased disease severity. The CDC’s experts also reported earlier this month that hospitalization rates appeared to be lower than they were last season. Azziz-Baumgartner cautioned that data lags could be muddying the picture, and officials have also been watching for any renewed spike in the spread of the flu. Some regions have also been reporting a strain on hospitals, especially in New England, he added. Just last week, Massachusetts General Hospital warned it was taking steps to address an "unprecedented overcrowding" crisis, along with other hospitals in the state. |

### Heart Disease Still America's Top Killer, Although the Death Rate Has Declined

Heart disease remains the United States' top cause of death, but progress is being made and more lives are being saved, a new report finds. There were 931,578 heart-related deaths in 2021, an increase of less than 3,000 from the year before, the report from the American Heart Association (AHA) showed. But overall, death rates from heart disease have declined 60% since the 1950s, AHA experts noted.

“When the American Heart Association was founded 100 years ago, heart disease was considered a death sentence. Little was known about what caused it and even less about how to care for people living with and dying from it,” said Dr. Joseph Wu, volunteer president of the American Heart Association. “The knowledge we continue to gain through research and data such as that reported in this statistical update is helping make significant inroads,” Wu, director of the Stanford Cardiovascular Institute, added in an AHA news release. “Although too many people still die each year, many are living longer, more productive lives while managing their cardiovascular disease and risk factors.”

Heart disease has been America’s top killer since before the founding of the AHA, researchers noted in the report published Jan. 24 in the AHA journal Circulation. However, the number of people who die from their heart attack each year has dropped from 1 in 2 in the 1950s to 1 in 8.5 now, thanks to improved diagnosis and treatment options for the medical emergency.

Progress also has been made against stroke, which was the third-leading cause of death in 1938 but now is the fifth-leading cause, the report noted -- thanks to better treatments and aggressive preventive measures. Cigarette smoking has also fallen dramatically. More than 40% of adults smoked in the mid-1960s, but only 11% smoke today.

“Identifying trends like this is a key reason why we compile the American Heart Association’s statistical update, which has been released annually since 1927,” said Dr. Seth Martin, chair of the AHA report committee and a cardiologist at Johns Hopkins School of Medicine, in Baltimore. Although progress is being made, it’s a rocky road, the report noted. Heart disease remains a major threat to the health of Americans.

For example, nearly half of the U.S. population -- about 49% -- have some type of heart disease, including clogged arteries, heart failure, stroke and, most notably, high blood pressure.

Nearly 47% of American adults have high blood pressure, but 38% of those with the condition are unaware they have it, the report found. During the past decade, the age-adjusted death rate from high blood pressure increased 66% while the actual number of deaths rose 91%.

“High blood pressure is a leading risk factor for heart disease and stroke, and yet with proper treatment and management it can be controlled and your risk for cardiovascular disease can be greatly reduced,” Wu said… Read More

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A new study may provide help to men newly diagnosed with prostate cancer who are faced with a daunting array of treatment options.

The study tracked 10-year outcomes and treatment side effects for nearly 2,500 men first diagnosed with prostate cancer in 2011 and 2012.

“Unlike previous studies, it focuses on contemporary treatment options,” explained study lead author Dr. Bashir Al Hussein Al Awamleh, a fellow in urologic oncology at Vanderbilt University Medical Center in Nashville, Tenn.

The study group was also diverse: About 1,800 of the patients were white, 350 were Black and 184 were Hispanic.

Patients were divided into two groups, based on how serious their disease was and their prognosis. Treatment offered to prostate cancer patients often differs based on prognosis.

Men with a "favorable" prognosis were offered four treatment options:

- **Active surveillance.** That's when men get no treatment, but their tumor is closely monitored in case it needs treating later on.
- **Nerve-sparing prostatectomy.** This involves delicate surgical removal of the prostate while leaving nerves involved in erectile function intact.
- **External beam radiation therapy (EBRT) -- using daily radiation to kill off cancer cells.**
- **Low-dose-rate brachytherapy.** Another approach using radiation, but this time it's delivered via implanted 'seeds'.

Men with an "unfavorable" prognosis got more aggressive treatments:

- **Prostatectomy -- full surgical removal of the prostate**
- **EBRT plus androgen-deprivation therapy (ADT).** ADT lowers a man's levels of circulating hormones, which can boost the effectiveness of radiation.

Among men with a "favorable" prognosis, those who opted for radical (full) prostate removal did have worse sexual function three to five years after the procedure versus those who went for other treatments, the Vanderbilt team found.

Urinary issues were also more common among this group: A quarter of all men who underwent prostate removal experienced "leakage" up to 10 years after the procedure, compared to just 4% to 11% of those who opted for EBRT. That was true for men in both the favorable and unfavorable groups.

For men in the unfavorable group, doctors saw no differences in sexual function whether they received prostatectomy or underwent EBRT/ADT.

Among men in the unfavorable group, EBRT/ADT was linked to slightly worse outcomes for bowel and hormonal issues at 10 years.

The study was published Jan. 23 in the *Journal of the American Medical Association.* All of these findings "underscore the importance of counseling men with unfavorable prognosis prostate cancer differently than favorable prognosis cancer regarding expected long-term functional outcomes," senior study author Dr. Daniel Barocas said in a Vanderbilt news release.

The findings also suggest "that adverse effects of treatments on sexual function may be de-emphasized in decision-making for some men," said Barocas, executive vice chair of urology at Vanderbilt.

He added that, for many men with a favorable prognosis for their cancer, "active surveillance" may still be the best route to go, "avoiding adverse effects associated with other treatment options."

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**Secrets For Staying Young, Healthy, And Fit As A Senior Citizen**

*What are your secrets for staying young, healthy, and fit at an old age (senior citizen)?* originally appeared on Quora: the place to gain and share knowledge, empowering people to learn from others and better understand the world.

**Answer by Lawrence Kosick, President and Co-Founder of GetSetUp, on Quora:**

Staying young, healthy, and fit in old age is a goal shared by many. While there is no one-size-fits-all approach, here are some secrets that can contribute to a vibrant and fulfilling life as a senior citizen. **Regular physical activity:** Engaging in regular exercise is vital for maintaining physical health, strength, and flexibility. It can help reduce the risk of chronic conditions, improve cardiovascular health, and enhance overall well-being. Activities such as walking, swimming, strength training, and yoga are excellent options for seniors to stay active and fit. Personally, I’m an avid runner and cyclist and work these sports into my travels and daily life.

**Balanced and nutritious diet:** A healthy diet plays a crucial role in maintaining overall health. It is important to consume a variety of nutrient-dense foods, including fruits, vegetables, whole grains, lean proteins, and healthy fats. Avoiding excessively processed foods, sugary snacks, and alcohol can help maintain optimal health and energy levels. The expression you are what you eat has never been more true, so make sure you are eating healthy whole foods and not overprocessed junk!

**Mental and cognitive stimulation:** Keeping the mind active and engaged is essential for healthy aging.** Read More**

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**‘Insuring’ good health -- the vital role of gym memberships for senior citizens: by Erin Troy**

As we age, the importance of maintaining good health becomes increasingly evident. Aging gracefully isn’t just a matter of genetics; it’s about making choices that promote a vibrant and active lifestyle.

One such choice that can make a significant impact is ensuring that older adults have access to gym memberships, often covered by insurance.

At the YMCA of Greater Cleveland, we firmly believe that insurance-paid gym memberships are a critical investment in the health and well-being of our aging population. Thousands of seniors take advantage of these memberships at our facilities.

In fact, more seniors whose YMCA memberships are paid by their insurance are visiting our branches today than they did pre-COVID.

Aging is an inevitable part of life, but it doesn’t have to mean declining health and quality of life. Regular physical activity plays a pivotal role in maintaining and improving health, especially as we get older. The benefits of exercise for seniors are well-documented: increased muscle strength, improved balance and flexibility, reduced risk of chronic diseases and enhanced mental well-being.

However, the barriers to engaging in regular exercise can be significant, particularly for those on fixed incomes. This is where insurance-paid gym memberships come into play as a game-changer.

First and foremost, insurance-covered gym memberships remove a financial hurdle that many seniors face. The cost of gym memberships, personal trainers or fitness classes can be prohibitive for older adults living on limited incomes.

By offering insurance coverage for gym memberships, we enable seniors to access these vital resources, making exercise more accessible and affordable. This, in turn, promotes long-term engagement in physical activity and ensures that exercise becomes a sustainable part of their daily routines.** Read More**
Strange visual disturbances occur early in about 10% of Alzheimer's cases, and when this happens it almost always signals the impending arrival of the disease, a new study finds.

The condition is called posterior cortical atrophy (PCA). It involves a sudden difficulty in performing vision-related tasks -- for example, writing, judging whether an object is moving or stationary, or easily picking up a dropped item. Everyday tasks like these become difficult despite the fact that a person's eye exam comes out fine.

“We need more awareness of PCA, so that it can be flagged by clinicians,” said study co-lead author Marianne Chapleau of the University of California, San Francisco's department of neurology.

“Most patients see their optometrist when they start experiencing visual symptoms and may be referred to an ophthalmologist who may also fail to recognize PCA,” she said in a UCSF news release. “We need better tools in clinical settings to identify these patients early on and get them treatment.”

To determine just how predictive of dementia PCA might be, Chapleau's team analyzed data on over 1,000 patients at 36 sites in 16 countries. PCA tended to emerge at a fairly young age -- 59, on average.

Patients with PCA often failed to accurately copy simple diagrams, had trouble gauging an object's location or had difficulty visually perceiving more than one object at a time, the research showed. Math and reading skills also began to falter.

In 94% of cases, people experiencing PCA went on to develop Alzheimer's disease, the UCSF team found. The remaining 6% developed other dementias such as Lewy body disease or frontotemporal lobar degeneration.

The researchers pointed out that's far more predictive of dementia than a condition such as memory loss: Only 70% of people with failing memories go on to develop dementia, they said.

Many people may show no cognitive issues when first stricken with PCA, but the study found that by about four years later, mild or moderate deficits in memory, executive function, behavior, and speech and language became apparent.

The findings were published Jan. 22 in The Lancet Neurology journal.

Renaud La Joie, also from UCSF’s department of neurology and the university’s Memory and Aging Center, is first author of the study. He believes that because PCA typically emerges years before actual dementia, it could point to patients who might be helped by newly approved Alzheimer's medications.

Some of those medications target tau, a protein that builds up in the brains of people with Alzheimer's disease.

### Do You Need to See a Doctor for That Rash?

When you worry about a rash?

Rashes may look alike, but while over-the-counter medications can treat some rashes, others can signal a more serious condition, the American Academy of Dermatology (AAD) says.

“It is important to watch your symptoms closely at the onset of a new rash,” said Dr. Mallory Abate, a board-certified dermatologist in Baton Rouge, La. “Making note of any changes or new developments are instrumental to determining the severity of the medical condition and if immediate assistance is needed.”

One key sign of bigger trouble is if you have a rash that is infected. Evidence of infection might include pus, yellow or golden crusts, pain, swelling, warmth or an unpleasant smell. The skin around an infection might look red, purple or brown, you might feel very hot or cold, have swollen lymph nodes, or a fever.

“If you have a rash and your symptoms are not improving, make an appointment to see a board-certified dermatologist,” Abate said in an AAD news release.

Abate and the AAD recommend people with rashes uses these clues to know when to seek medical attention:

- A rash over most of your body.
- A rash that blisters or turns into open sores or raw skin.
- Fever or illness with a rash.
- A rash that spreads rapidly.
- A painful rash.
- A rash involving the eyes, lips, mouth or genital skin.
- If you have trouble breathing or swallowing, or your eyes or lips swell up, emergency medical care may be necessary and should be sought immediately.

### Philips Suspends U.S. Sales of CPAP, Ventilator Machines After Recall

Following a recall of millions of its breathing machines that began in mid-2021, Philips Respironics announced Monday that it would halt sales of all such machines within the United States.

The machines include continuous positive airway pressure (CPAP) devices used by people with sleep apnea, as well as ventilators used by other patients.

The recall was first spurred in 2021 by reports of defective CPAP machines emitting bits of foam and potentially toxic gases back into users’ airways.

At the time, Philips initiated a recall of the devices in June 2021 and put a pause on sales of new sleep therapy machines to U.S. customers, Philips spokesman Steve Klink told the New York Times.

After that, Philips published data from follow-up testing that it said showed the devices were “not expected to result in appreciable harm to health in patients,” although further testing was ongoing.

However, the U.S. Food and Drug Administration questioned the validity of those claims, calling them " unpersuasive," the Times said.

Although the 2021 recall affected about 15 million devices manufactured since 2006, over 5 million more were thought to be still in use by 2021, the Times said.

Many thousands of U.S. patients and their families who used the breathing machines have sued Philips, blaming the faulty devices for a wide range of ailments, including fatal lung cancers.

According to the Times, in September the company reached a $479 million settlement with patients meant only to cover the cost of repairing and replacing machines. Separate litigation over illnesses and related medical costs is still working its way through the courts.

Under the agreement reached Monday with the FDA, Philips is obliged to meet a list of standards before it might resume sales in the United States. The company pledges to repair and service devices already in use, the Times added.

Philips said sales of the devices in other countries would continue.