In The News
- Virus Testing Shortfalls Cause Lines to Build in Hard-Hit States
- Virus Threat Grows in U.S. Where Millions Lost Health Coverage
- Hard-Hit States Plan Testing Surge of Asymptomatic Young People

Inside CMS
- Hospitals Lose Legal Skirmish Over Price Disclosure Requirement

Legislative/Regulatory
- Grassley to Renew Drug-Pricing Push ‘With or Without Democrats’
- House Passes Obamacare Upgrades to Bolster Democratic Campaigns
- Covid Mental Health Fallout Spurs House Bills to Fund Assistance
- Trump’s Surgeon General Says ‘Please, Please, Please’ Wear Mask
- Fauci Says U.S. Risks 100,000 Daily Cases in Dire Warning
- FDA Covid Vaccine Guidance Throws Cold Water on Trump 2020 Goal

Legal
- Hospitals Lose Bid for Attorneys’ Fees in Medicare Bad Debt Case
- Obamacare Backers See Hope in Roberts Opinion in Non-Health Case
- Class Certification Over Medicaid Repayments Reversed in Ohio

Around the States
- Michigan: Health Workers to Get Pay Bump Under Michigan Covid Relief Law
- New York Opening Virus Testing to All Residents, Cuomo Says
- Oklahoma: Rural Hospitals Get Boost From Oklahoma Vote To Expand Medicaid
IN THE NEWS

**Virus Testing Shortfalls Cause Lines to Build in Hard-Hit States**

The U.S. is again grappling with a shortfall of testing that has hobbled the nation since the pandemic’s early weeks, and now threatens to further undermine containment efforts at a crucial moment. In new hot spots like Arizona, Texas and Florida, where Covid-19 is rapidly spreading, lines for testing extend outside of urgent-care offices and other sites. Two high-school football stadiums in Houston regularly hit capacity by mid-morning and have to turn people away.

The country’s largest labs are forecasting a surge in demand that could lead to longer waits for test results, and have warned that limited amounts of critical testing supplies could become a constraint. Though capacity has expanded, widespread testing remains elusive, in part due to persistent supply shortages. “We are still grossly inadequate. We’re so far behind,” said Howard Forman, director of the Yale School of Public Health’s health-care management program. “We still have a supply issue, and then we had a demand issue. You have both issues playing out. At the federal, state and local level, you need both those things addressed.”

The testing dearth comes months into a public-health crisis in which, absent a vaccine, Covid-19 screenings have become the first line of defense. Reopening states only turned up the pressure, boosting demand for testing as Americans increasingly went back to work, ate out, got haircuts and gathered socially.

The surge in cases has forced states to reconsider their reopening efforts. New Jersey Governor Phil Murphy on Monday paused plans to restart indoor dining on July 2. New York Mayor Bill de Blasio and New York Governor Andrew Cuomo also said skyrocketing cases in the South and West have prompted them to consider postponing dining’s return. U.S. virus deaths have exceeded 125,000 out of more than 2.5 million reported cases.

The pause in reopening was endorsed by Larry Kudlow, the top White House economic adviser. And Senate Majority Leader Mitch McConnell on Monday joined Vice President Mike Pence in encouraging the public to wear masks. On Tuesday, top federal health officials including infectious-disease expert Anthony Fauci are expected to appear at a Senate committee hearing to discuss efforts to get back to work and school. Worldwide, deaths have surpassed 500,000. The World Health Organization said “the worst is yet to come” as some countries see a resurgence of cases. Half the deaths are coming from the Americas.

The irregular reopening in the U.S. reflects the two-steps forward, one-step back pace seen elsewhere. In the U.K. and Germany, authorities have reimposed strict lockdown measures on areas affected by local infection clusters. Arizona Governor Doug Ducey announced on Monday that the state would pause operation of bars, gyms and movie theaters as well as tubing and water parks. Ducey said he is targeting reopening in 30 days. Crisis standards of care were put in place and hospitals were told to prepare for a surge, Arizona Department of Health Services Director Cara Christ said.

The shortfalls in U.S. testing availability highlight the Trump administration’s failure to execute a cohesive national strategy. The burden shifted to states, which were provided some testing supplies in May and but have been told only limited amounts are available thereafter. The U.S. processed about 557,000 tests each day, on average, over the last week, according to the Covid Tracking Project. Given the size of the current U.S. outbreak, 2 million to 4 million tests a day would be needed “to do something to really wipe it out,” Forman estimated. “We’re not really close to that.”
In Texas, which is quickly becoming the new U.S. epicenter, the strain from increasing testing demand was felt by hospitals, public-health departments and patients alike. Houston Mayor Sylvester Turner said capacity at the Delmar and Butler stadium sites will be expanded by 30% starting Tuesday. A line that started before 5 a.m. Sunday at an urgent-care center in South Austin was compared to the wait for a wristband to Austin City Limits, the city’s annual music festival, or the queue for barbecue at Franklin’s, which would draw dozens customers to its doors before sunrise.

Kaitlin Heikes, a 26-year-old San Antonio resident, had to drive 45 minutes to Spring Branch for a rapid test. She made an appointment on Sunday for the following day after she didn’t have any luck on Friday or Saturday. At the Houston Methodist hospital system, demand for testing doubled over the last week or so, David Bernard, medical director of clinical pathology, said in a Friday interview. The lab has faced an uphill battle securing supplies, and equipment is needed after diagnostics companies initially prioritized early hot spots like New York. “We’ve been stretched,” Bernard said. Test manufacturers “don’t give you as much as you want, and it’s been a struggle. We’ve had to work as hard as we can to get things done.”

Covid cases are on the rise in Harris County, home to sprawling Houston, which for a time had been able to meet demand, said Umair Shah, executive director of Harris County Public Health. “We’re doing everything we can to meet or increase capacity,” Shah said in an interview. “But it is not enough right now.” A local Texas health department was still receiving test results by fax as recently as last week, slowing them down further, said David Lakey, UT System’s vice chancellor for health affairs and chief medical officer and the former commissioner of the Texas Department of State Health Services. “If we had today 6,400 new cases and you have that kind of volume each day, there isn’t possibly a way for the staff of the local health departments” to do contact tracing, he said. “They are getting overwhelmed right now.”

California has experienced delays, too. Barbara Ferrer, who directs Los Angeles County’s health department, said in an interview that some testing centers can take a week to report results, also creating problems for contact tracing. At that point, those who test positive will have had days to go around infecting more people before the county can talk to them and the people around them, Ferrer said. Los Angeles County counted its highest daily totals of new cases and people who are hospitalized due to the virus, Ferrer said at a daily briefing Monday. The seven-day average rate of positive tests has jumped to 8.4% from 4.6% in late May, the county said in a release.

In Florida, hundreds of cars have been lining up at test centers. Health officials said wait times could be up to four hours on Monday at the Hard Rock Stadium site serving the Miami metropolitan area, and the Orange County Convention Center site in Central Florida had waits of about five hours. In St. Petersburg, local police said a site at Tropicana Field ran out of tests only about an hour due to “overwhelming turnout.” “The testing capacity is disappointing,” St. Petersburg Mayor Rick Kriseman wrote in a tweet. “We are working with the state to bring additional, expanded testing.”

**Virus Threat Grows in U.S. Where Millions Lost Health Coverage**
As a second coronavirus wave threatens America, millions are stranded without health insurance after losing their jobs when the disease first hit.

More than half the U.S. population relied on the workplace for health coverage, before a pandemic that’s triggered record job losses worldwide. In other developed economies, the newly unemployed could rely on systems of universal health care. In America, they’ve had to navigate a bewildering menu of options to figure out if they have access to a patched-together safety net. While Congress has set aside billions of dollars to pay for virus-related care for the uninsured, they’ll be on their own for more ordinary medical
expenses. “With health insurance in particular, we have a social support system that really isn’t very functional when you have job loss,” said Ben Zipperer, an economist at the Economic Policy Institute in Washington. That’s a problem at the best of times, he said, “but it’s a real disaster when you have tens of millions of workers suddenly lose their job.”

The Covid-19 shock had likely pushed more than 16 million workers off employer-provided health insurance as of early May, the left-leaning EPI estimates. Unemployment data for June, due Thursday, will shed more light on the picture. Including dependents like spouses and children, the Kaiser Family Foundation estimated that almost 27 million people could have lost their employer-sponsored coverage and become uninsured between March and May. It said that while most of those are eligible for some kind of subsidized coverage through Medicaid or the Affordable Care Act marketplaces, about 5.7 million probably aren’t.

The ACA, known as Obamacare, aimed to broaden coverage in two main ways. For households with low or moderate incomes, it offered subsidized private plans that could replace job-based coverage. The 2010 law also expanded Medicaid, a program that offers free health insurance for the poorest Americans, to include those slightly above the poverty level. But 14 states — including Texas and Florida, where coronavirus cases have been soaring — opted out of the latter provision. In those places, it’s been especially easy to fall through cracks in the system.

That’s what happened to Emily, whose asthma puts her in a high-risk group from Covid-19, after she was laid off from her sales job in Houston in March and lost health insurance. Her husband is also out of work, and she asked not to be identified by her surname discussing personal details while she’s seeking employment. Emily had the option of keeping her workplace plan at her own expense under a program called Cobra, which allows Americans to extend employer-provided health coverage after a job loss. But she said that would have cost almost $2,000 a month for her and her husband.

The couple didn’t qualify for Medicaid in Texas — a state which had the highest share of uninsured people in the country as of 2018. Meanwhile, Emily’s application for unemployment insurance wasn’t approved till June. And that delay in turn meant that she fell short of the minimum income threshold for subsidies under the ACA, she said, which would have cut the cost of buying a plan on state exchanges to about $180 a month, from $450. Her conclusion: “The system is not set up to really help people.”

About 27.5 million Americans, or 8.5% of people, were uninsured in 2018. The numbers are down sharply by comparison with the pre-ACA years, and the reform probably helped prevent a bigger spike in the numbers during the pandemic, too. How affordable its provisions are is a different question. Brian Smith, 44, played double bass in the Indianapolis Symphony Orchestra before he was furloughed in March when performances shut down. Smith initially kept his health insurance, because he was getting partial pay after his employer got a Paycheck Protection Program loan. But it ran out June 7, and the orchestra’s 76 musicians and librarians lost their coverage.

Going without insurance wasn’t an option for Smith, who needs physical therapy after breaking an elbow bone in May, and has a child with asthma. But “my costs are significantly higher” just when income has dried up, he said. “I’m one of millions of people that’s dealing with this.” While U.S. unemployment has already begun to fall back from the highest levels since the Great Depression era, it may take longer to close the new gaps in health insurance.

Companies added 3.1 million workers back onto payrolls in May, likely helping many to regain employer-provided health insurance. But much of the re-hiring was in industries like hospitality and retail that are
relatively less likely to offer such benefits -- a trend that’s expected to continue in the June data coming this week.

Meanwhile, some 6 million white-collar jobs, from professional services to real estate, are vulnerable to a second wave of layoffs. State and local governments continued to cut staff in May, and may be forced into further reductions as revenues decline. About two-thirds of public-sector workers were covered by health insurance through their employer in 2018, according to EPI. “It’s probably a safe bet to think that this is still going to be a disaster that’s unfolding,” Zipperer said. A recent survey by the Commonwealth Fund found that among adults who had insurance through their workplace, and saw their job disrupted by the pandemic, one in five said they or their partner are now uninsured.

Zachary Seif in Evansville, Indiana, has been without coverage for about two months, since he was permanently laid off from his job selling furniture a month after being furloughed. Due to a mistake on the unemployment insurance application by his former employer, Seif says, he still hasn’t received any of the money. Even so, he says he doesn’t qualify for Indiana’s Medicaid program. “It is super unfortunate to be at that cutoff,” he said. It’s “an arbitrary number because everybody’s expenses and costs are different.” Seif has leaned on his still-employed fiancée, and a philanthropist he reached out to on Twitter, to pay for two months of his medications. He has a new job lined up at a car dealership starting in July -- which would mean that two months later, he’ll once again be getting health insurance via his employer.

**Hard-Hit States Plan Testing Surge of Asymptomatic Young People**

Federal health officials are planning “surge testing” of asymptomatic residents in states that have seen a spike of new Covid-19 cases, particularly those 35 years old or younger.

It’s “very clear” new cases are being driven by younger people, Assistant Health Secretary Brett Giroir, who is leading the testing programs, told reporters Wednesday. The strategy would be to conduct “the number of tests you’d do in a month in just a few days” to identify potential asymptomatic Covid-19 carriers. Right now federal officials are trying to organize surge testing with state officials in Texas, Louisiana, and Florida, among others.

A testing barrage of entire communities regardless of whether they feel sick will help supplement the data collected through contact tracing, which is difficult to do with outbreaks that don’t appear to be tied to a single facility or event, Giroir said.

**INSIDE CMS**

**Hospitals Lose Legal Skirmish Over Price Disclosure Requirement**

The Trump administration can keep its rule requiring hospitals to disclose the prices they privately negotiate with insurance companies, a federal district court held.

The U.S. District Court for the District of Columbia Tuesday rejected hospital industry groups’ claims that the Department of Health and Human Services issued a rule that was arbitrary and capricious, exceeded its rulemaking authority, and violated the First Amendment by mandating speech that fails to directly advance a substantial government interest.

The court instead granted the Trump administration’s motion for summary judgment. It upheld the rule, which is a policy the administration has been pushing in an effort to shine a light on hospital pricing.
The challenge by four of the nation’s leading health-care industry groups, including the American Hospital Association, and three hospitals centered on how the agency defined standard charges that a hospital must list publicly. “It is a close call whether the agency reasonably interpreted ‘standard charges’ to include rates negotiated with third-party payers,” Judge Carl Nichols said. “After all, the more charges published for any one item or service, the less any one of those charges can be considered ‘usual’ or ‘customary.’” But, he said, “in this exceptionally unique market, the Court cannot conclude” that the Centers for Medicare & Medicaid Services’ interpretation is unreasonable.

The amounts paid to hospitals for items and services differ across patient groups, which have varying economic relationships with both hospitals and third-party payers, Nichols said. “The agency’s decision to define ‘standard charges’ based on the different patient groups is thus a reasonable construction that accounts for the peculiar dynamics of the health care industry,” he said.

The rule requires some 6,000 U.S. hospitals to publicly provide their negotiated rates with insurers for 300 common medical services, along with the discounted cash price they’re willing to accept for those procedures. The American Hospital Association said it will appeal and seek an expedited review of the ruling. “The proposal does nothing to help patients understand their out-of-pockets costs,” Melinda Hatton, AHA’s general counsel, said in a statement. “It also imposes significant burdens on hospitals at a time when resources are stretched thin and need to be devoted to patient care. Hospitals and health systems have consistently supported efforts to provide patients with information about the costs of their medical care. This is not the right way to achieve this important goal.”

In a tweet Tuesday afternoon, HHS Secretary Alex Azar called the ruling a big victory for the president’s health-care agenda. “With this decision, we will continue to deliver on President Donald Trump’s promise for ‘A+’ transparency and lower costs for American patients,” he said. CMS Administrator Seema Verma fired off her own tweet, assailing the litigation. “This was a disingenuous self-serving lawsuit designed to keep patients in the dark,” she tweeted.

Patient Rights Advocate.Org, a group fighting for price transparency in health care, said the court’s ruling forces hospitals to compete on quality, performance, and at the best price just like any other business. “It’s overwhelmingly in support of common sense that all Americans deserve the right to see prices to be in control of their health care decisions,” Cynthia Fisher, the group’s founder and chair, said in an interview. “The judge ruled in favor of all of us.” Competition in a functional marketplace drives down costs and improves quality, Fisher said. “We’ve seen it in technology, we see it in groceries, we see it in retail, we see it in airlines, we’ve seen it in every other facet of our lives, and now we’re going to be able to see it in health care,” she said.

The industry groups had argued the rule will chill negotiations between hospitals and insurers. But Nichols said in his opinion that the rule only requires hospitals to disclose their final agreed-upon price—which each patient already sees in their insurance-provided explanation of benefits—and not any information about the negotiations themselves. “Plaintiffs are essentially attacking transparency measures generally, which are intended to enable consumers to make informed decisions; naturally, once consumers have certain information, their purchasing habits may change, and suppliers of items and services may have to adapt accordingly,” he said.

Grassley to Renew Drug-Pricing Push ‘With or Without Democrats’
The chairman of the influential Senate Finance Committee will push for a vote on his drug-pricing measure without the help of critical allies: Senate Democrats.

Chuck Grassley (R-Iowa) will re-introduce a drug pricing package (S. 2543) he assembled with the ranking member of his committee, Ron Wyden (D-Ore.), and soon call on Senate leaders to allow debate on the measure, Grassley spokesman Michael Zona said. The senator, term-limited as chairman of the Finance panel after this year, wants his measure included in the next coronavirus legislation and plans to move ahead "with or without Democrats,” Zona said.

The Covid-19 pandemic has both heightened the urgency of reining in pharmaceutical costs yet also made it harder for lawmakers to act. Drugmakers say limiting their profits could hamper efforts to create a vaccine against the virus, but medicines to treat it come with significant price tags. Gilead Sciences Inc. set the price for its widely used Remdesivir at $2,340 for a five-day treatment. Both parties, with control of the Senate up for grabs in the November elections, swapped blame for inaction on drug prices. “Democrats have left the negotiating table” at the urging of party leaders, Grassley said. “I can only assume the Democratic Party would rather use the issue of drug prices as a political hammer in November’s election than work to address it now,” he said in an op-ed in the Wall Street Journal Monday. “Perhaps they hope to pass more left-leaning legislation next year, if they win more power.”

Democrats are “not interested in aiding Republicans as they play political games and pretend to support lowering prescription drug prices,” Wyden said. “Democrats have not walked away from the table on drug pricing—Republicans never showed up in the first place,” Wyden said in a statement. He said there’s no reason to expect the GOP-led chamber to allow a vote on the Grassley-Wyden bill.

Wyden noted that the House passed a measure to direct the government to demand lower prices from drugmakers last year (H.R. 3). Senate leaders, including Grassley, have said they won’t support that bill. Garnering support for the legislation, which would cap drug costs for Medicare beneficiaries and force drug manufacturers to provide Medicare inflation rebates, has been an uphill battle for Grassley over the past year.

He gradually gained backing from more of his fellow Republicans in the Senate, often persuading them one-by-one to make shows of support since last summer. Democrats in the Senate were essential to getting the legislation even out of the Finance Committee, which approved it with the support of 13 Democrats and six Republicans in July 2019.

Grassley has previously said he needs at least 25 Republican co-sponsors to get his bill to the floor and sees backing from the White House as important in getting more votes. About a dozen Republicans other than Grassley have so far publicly expressed support for the legislation. Grassley said he asked President Donald Trump earlier this month in a caucus meeting if he would support his legislation. Trump, who has backed the bill, gave an “emphatic yes,” Grassley said.

The Grassley-Wyden package would create a rebate system in Medicare Part B and Part D beginning in 2022 for brand-name drugs and biological products with prices that increase faster than inflation. Conservative groups and some Senate Republicans have opposed the rebate system for Part D, the prescription drug benefit program, but not for Part B, the outpatient services program.
House Passes Obamacare Upgrades to Bolster Democratic Campaigns
Legislation to boost Obamacare subsidies and direct the government to demand lower prices on certain drugs won House passage Monday, in an election-year reprise of earlier votes that Democratic leaders engineered to highlight differences with the Republican-controlled Senate and the Trump administration.

The bill (H.R. 1425) would expand the Affordable Care Act’s tax credits, pressure states to expand Medicaid programs with the promise of more federal funds, and cap what any person may pay for coverage premiums at 8.5% of income. It would also let immigrants living in the U.S. under the Deferred Action for Childhood Arrivals program get access to subsidized insurance plans.

The bill stands no chance of becoming law in the current Congress, but Democratic leaders said they’re making good on a 2018 campaign promise to protect the Affordable Care Act. “When Democrats won the majority in the House, we did so promising to work to expand coverage, lower out-of-pocket costs, and provide greater stability for health insurance marketplaces,” House Majority Leader Steny Hoyer (D-Md.) said on the floor. “That’s what we promised and we picked up 40 net seats. This bill as part of that promise. Now we pass another one.”

The bill passed 234 to 179.

The package combines bills that have already passed the House (H.R. 987; H.R. 3) this Congress but the Senate hasn’t taken up and that the White House has signaled President Donald Trump would veto if it either reached his desk. Republican leaders said Democrats aren’t serious about improving the Affordable Care Act and warned that the legislation’s drug-pricing provisions would stymie investments in innovative new medicines. “They find the political fear mongering to be too potent in an election-year weapon,” said Rep. Kevin Brady of Texas, the top Republican on the Ways and Means Committee. “So, we continue this charade.”

The House package, like many health bills the chamber has passed this year, has most Democrats’ support but wouldn’t go as far as some in the party would like to extend government negotiation on drug-pricing or the government’s role in providing health coverage.

Rep. Lloyd Doggett (D-Texas) called the bill “exceedingly modest” in its approach to drug pricing. Other Democrats have said they think the spread of the coronavirus warrants creating a single-payer health system where the government would replace much of the private health insurance industry. “The exceedingly modest pharmaceutical provision in today’s bill excludes the uninsured and falls well short of what is needed to prevent monopoly prices for drugs,” Doggett said.

Reps. Pramila Jayapal (D-Wash.) and Mark Pocan (D-Wis.), in a statement, welcomed the Affordable Care Act improvements. Still, they said, what’s needed is to “untether health care from employment and take on our corrupt, for-profit health care system that has widespread and damaging ramifications for public health.”

Covid Mental Health Fallout Spurs House Bills to Fund Assistance
Federal mental health assistance may gain traction in the House as lawmakers consider expanding Medicare for some services and creating behavioral health grants for areas with Covid-19 surges. Mental health and substance abuse treatment advocates say they need money to help clinics and health-care providers stay in business as the coronavirus pandemic keeps many from seeking treatment. “We need to keep the lights on,” said Andrew Kessler, founder and principal of Slingshot Solutions LLC, a consulting firm that specializes in behavioral health policy.
The U.S. was already facing a mental health and addiction crisis before the pandemic struck: Suicide and drug overdoses killed more than 100,000 Americans annually between 2015 and 2019, according to the Centers for Disease Control and Prevention.

The House Energy and Commerce Health Subcommittee reviewed 22 mental health bills Tuesday and Democratic leaders signaled the legislation could come to the House floor this year, possibly as part of the next coronavirus-relief package. Frank Pallone (D-N.J.), chairman of the committee, said he expects the bills to get votes.

Democrats blamed the Trump administration for failing to send already-appropriated money to behavioral health providers. Congress appropriated funds but the government has “been too slow to release them,” said Rep. Anna Eshoo (D-Calif.), chair of the Health Subcommittee.

In 2018, 128 people died in the U.S. after overdosing on opioids, CDC data show. Drug overdose fatalities rose by more than 10% for the first four months of 2020 compared with the same period in the previous year, according to the White House Office of National Drug Control Policy. The spread of the coronavirus has fueled cases of anxiety and depression. One survey, by Mental Health America from February, found 88,000 more Americans nationwide were found to have anxiety or depression compared with just three months before.

Many drug treatment centers and mental health providers are struggling financially, and have yet to benefit from government funds for those affected by the coronavirus. Congress appropriated $175 billion to provide Covid-19-related relief to hospitals and other health providers in the CARES Act (Public Law 116-136). The Department of Health and Human Services has given out roughly $112 billion so far. Most of the distributions have been built around Medicare, sending money to providers based on their previous Medicare revenue, Kessler said. Behavioral health providers, particularly substance abuse treatment providers, typically handle far more beneficiaries of Medicaid, the health-care program for the poor, than those covered by Medicare, which serves the elderly and disabled, he said.

Mental health services have been “chronically underfunded” in the U.S. for decades, Patrick Kennedy, a former congressman and Founder of the Kennedy Forum, a behavioral health advocacy group, told the committee. This year Congress has dedicated $425 million to behavioral health through the CARES Act, yet the economic decline created by the spread of the virus likely will result in billions of dollars in cuts to Medicaid by states in the next year, Kennedy warned. Funding for behavioral health amounts to less than 1% of the total spending in the CARES Act, he said. “It all revolves around the money,” he said. “As we know you see what’s important based on what you spend your money on.”

Republicans and Democrats on the panel agreed that Congress needs to address the mental health challenges worsened by the coronavirus, yet differed over more than half the bills the panel reviewed. Rep. Greg Walden (R-Ore.) said Republicans support nine of the bills, including one (H.R. 7316) to create a special center for training mental health providers and another (H.R. 7293) to expand suicide awareness and training in schools.

Rep. Michael Burgess (R-Texas) said he doesn’t support a measure (H.R. 884) that would give more independence to clinical psychologists to treat Medicare patients without approval from a physician, because it would expand the definition of a physician under Medicare. Eshoo said the bills would help health-care providers better meet the increasing demand for their services.
“The pandemic is fueling mental health problems while also hurting the ability for caregivers to deal with the crisis,” the California Democrat said.

**Trump’s Surgeon General Says ‘Please, Please, Please’ Wear Mask**
The Trump administration’s coronavirus task force stepped up its calls for Americans to wear masks as cases surge in some states but Vice President Mike Pence said there are no plans to override governors who have yet to require them. “Please, please, please wear a face covering when you go out in public,” Surgeon General Jerome Adams, a member of the task force, said at a briefing Tuesday.

Adams delivered the strongest plea to the public yet from an administration that has often sidestepped direct recommendations to wear masks. Health and Human Services Secretary Alex Azar and Pence both urged wearing a mask at the event in Rockville, Maryland, though Pence only said to do so if local authorities recommended it. Pence himself wore a mask before he began speaking.

Several Southern and Western states are seeing an escalation in new case numbers, prompting some to put off reopening plans. The call for masks came on the same day infectious-disease expert Anthony Fauci told a Senate panel that the U.S. is “going in the wrong direction” in its effort to contain the novel coronavirus and daily case counts could more than double if behaviors don’t change.

Pinpointing indoor gatherings, particularly bar scenes with lines out the door and patrons standing shoulder to shoulder, Fauci said new cases of Covid-19 could rise to 100,000 a day, up from the current level of about 40,000. Pence said to “wear a mask, wherever it’s indicated or wherever you’re not able to practice the kind of social distancing that would prevent the spread of the coronavirus.” He also made it clear that there are no plans to issue national requirements on masks, allowing states to manage their “unique circumstances.”

“And we’ll continue to use that model, respecting the decisions that governors are making,” Pence said. But Adams called for Americans to wear masks -- not just where there are mandates to do so -- and said the face coverings don’t restrict freedoms.

“It actually is a vehicle to achieve our goals, it adds to your convenience and your freedom, because it allows us to open up more places and it allows those places to stay open,” he said. President Donald Trump has mocked his Democratic challenger Joe Biden for wearing a mask and has never publicly worn one, though he is facing calls to do so. In some parts of the country, the issue has gone from a health issue to a political one.

In Colorado later Tuesday, Governor Jared Polis said he thought “there’s been a breakthrough because you have Mike Pence wearing a mask. You have the governor of Texas and Arizona saying everybody needs to wear a mask. These are staunch conservative Republicans. This is not an ideological and partisan thing. It’s a science thing.” “For a while, unfortunately, like too many things across society, it all seemed to become like an ideological thing or even a party thing,” Polis, a Democrat, told reporters in Denver.

**Fauci Says U.S. Risks 100,000 Daily Cases in Dire Warning**
The U.S. is “going in the wrong direction” in its effort to contain the novel coronavirus and daily case counts could more than double if behaviors don’t change, infectious-disease expert Anthony Fauci said Tuesday. Pinpointing indoor gatherings, particularly bar scenes with lines out the door and patrons standing shoulder to shoulder, Fauci told a Senate panel that new cases of Covid-19 could rise to 100,000 a day, up from the current level of about 40,000.
Several southern and western states are seeing surging new case numbers, prompting some to put reopening plans on hold. Hospitalizations have increased in 12 states, Centers for Disease Control and Prevention Director Robert Redfield told members of the Senate health committee. Florida’s Miami-Dade County reported its highest numbers of hospitalizations, intensive-care patients and ventilator use in at least two months. In Houston, ICUs hit 97% of normal capacity on Tuesday.

“The numbers speak for themselves. I’m very concerned. I’m not satisfied with what’s going on because we’re going in the wrong direction,” Fauci, the director of the National Institute of Allergy and Infectious Diseases, said. “Clearly we are not in total control right now.” He declined to estimate the number of potential deaths from the virus but said, “It is going to be very disturbing, I guarantee you that.”

Tracking the Spread of the Coronavirus Outbreak in the U.S.

As the evidence from the U.S. points to an outbreak that’s averted control, European Union governments extended a travel ban, meaning U.S. citizens aren’t allowed to enter for non-essential reasons. Texas reported a record in new cases on Tuesday and California its second-biggest daily jump. Both states took steps recently to rein in the new surge, with California requiring masks and Texas closing bars. On Monday, Arizona paused operations at bars, gyms and movie theaters. Florida, which had an average 5.6% rise in cases over the past week, banned the consumption of alcohol in bars on Friday. Meanwhile New York, New Jersey and Connecticut, hot spots earlier in the pandemic, added 16 states to their self-quarantine orders for visitors.

As many as 36 states have R0 figures above 1, up from 31 states a week ago, according to the Rt.live website. That means each person with the coronavirus infects at least one other. Rt.live is a site made by the co-founders of Instagram and uses data derived from public health bodies. More than 40% of the U.S. has now reversed or halted economic re-opening moves, according to estimates by Goldman Sachs Group Inc. economists.

Vice President Mike Pence sought to strike a more positive tone later Tuesday in comments after meeting with the coronavirus task force in Rockville, Maryland. The U.S. is “in a much better place” than several months ago. “To every American, we want to assure you that we’re ready,” he added. “More ready than ever before.”

In the strongest push yet by the Trump administration in favor of using face coverings to contain the virus, Surgeon General Jerome Adams, speaking at the same briefing, said, “Please, please, please wear a face covering” when going out. “It is not an inconvenience. It is not a suppression of your freedom,” Adams said. “It adds to your convenience and your freedom because it allows us to open up more places and allows them to stay open.” While Pence also encouraged using masks, he didn’t make as full-throated an endorsement as Adams. He urged people to cover their faces according to recommendations from their local authorities and when they can’t social distance.

During the hearing earlier, Senator Lamar Alexander of Tennessee, chairman of the committee, said that wearing masks shouldn’t be a political statement. He spoke about needing to self-quarantine after a member of his staff was diagnosed with the virus and said the Senate physician credited the staffer’s mask with protecting Alexander from infection. “Unfortunately this simple lifesaving practice has become part of a political debate that says: If you’re for Trump, you don’t wear a mask. If you’re against Trump, you do,” Alexander said.
The key is for the public to stop what Fauci called “an all-or-nothing phenomenon,” meaning either a state is locked down or people are in bars without masks on. “I think we need to emphasize the responsibility we have as individuals and as part of a societal effort to end the epidemic and we all have to play a part in that.” Pence said in his comments later that he agreed with Fauci. “We should not look at public safety measures as an impediment to opening up America but rather we should look at them as a vehicle to opening up,” he told reporters.

Redfield told the Senate panel that companies also need to insist on social distancing and masks. American Airlines Group Inc.’s announcement on Friday that it would resume selling flights to capacity on July 1 rather than capping passengers to keep them socially distanced caused “substantial disappointment” among public health officials, he said.

The U.S. has recorded more than 2.6 million Covid-19 cases in total, with more than 126,000 deaths from the virus, according to data compiled by Johns Hopkins University. As for returning students to school, Fauci said institutions may need to consider online classes or staggered schedules to safely bring students back. While children appear to respond less severely to Covid-19 than adults, it’s still unclear whether they could become vectors to spread the virus to teachers and family, something health agencies are studying and hope to have more data on, he said. Speaking after the taskforce meeting, the surgeon general said that masks will be essential for any return to school. “If you want the return of college football this year, wear a face covering,” Adams said. “If you want a chance at prom next spring, wear a face covering”

Several drugmakers are racing to complete clinical trials of vaccine candidates, with some expecting to wrap up in months studies that under previous circumstances have tended to take years. The Food and Drug Administration laid out standards for approving an inoculation, saying any candidate would have to be at least 50% more effective than a placebo.

Fauci said that he’s “aspirationally hopeful” that a vaccine for Covid-19 will be ready in early 2021, though he cautioned that there’s no guarantee that a safe vaccine will be developed. Some health experts have expressed worry that FDA will rush to approve a vaccine before enough is known about safety or efficacy but the agency sought to allay those fears with the guidance. “The American people should know that we have not lost sight of our responsibility to maintain our regulatory independence and ensure that our decisions related to all medical products, including those related to Covid-19 vaccines, are based on sound science and the available data,” FDA Commissioner Stephen Hahn told the panel.

**FDA Covid Vaccine Guidance Throws Cold Water on Trump 2020 Goal**

The Food and Drug Administration’s new standards on Covid-19 vaccine development may dampen Wall Street hopes that a shot to prevent the spread of the pandemic will be available before the U.S. election in November.

With the FDA’s standards for an emergency use authorization not much lower than what’s needed for full approval, the first authorization seems more likely to happen in early 2021, said Geoffrey Porges, an analyst with SVB Leerink.

The agency’s guidance, published on Tuesday, said any vaccine candidate would need to prove itself at least 50% more effective than a placebo to earn an approval, and that merely showing immune response data would not be enough.
“It is hard to see how those studies could enroll thousands of patients, vaccinate them, and then observe them for safety for six months or more, and then be approved” before the end of the year, Porges wrote in a note to clients. A fully approved vaccine will need “extensive safety data, and full clinical efficacy,” he said. Investors were anticipating the first vaccine might arrive in the autumn after reports of President Donald Trump pressuring health officials in his re-election bid. Drug and vaccine developers including Johnson & Johnson, Merck & Co., Pfizer Inc. and Moderna Inc. are taking part in the administration’s “Warp Speed” program. The government program is meant to further efforts to develop a vaccine faster than any have been developed before, though details are scant.

Pfizer rallied as much as 5.6% on Wednesday after early data with partner BioNTech SE showed promising effects for a vaccine candidate, while small-cap vaccine developer Inovio Pharmaceuticals Inc. plunged 27%. Moderna, one of the leaders in the space, fell 7.9%. All three vaccine programs would likely need longer-term results to clearly establish safety, according to Porges. DNA vaccines in particular, like Inovio’s, may be “held to a more stringent standard given general concerns about risks of genetic integration.” Porges doesn’t see a 2020 vaccine happening, and “the success of that effort is by no means a foregone conclusion,” he said. Instead, he predicts a full vaccine approval may come in another two or three years, with widespread adoption taking another year after that.

Should a vaccine be approved, getting enough Americans to vaccinate will be another hurdle to turning the tide on Covid-19. Yesterday’s guidelines are meant to depoliticize the government’s vaccine efforts so people aren’t afraid to get vaccinated, Beacon Policy Advisors founder Brandon Barford said in a phone interview. “They are trying to put out very prescriptive guidelines so outside experts can quickly try to validate the studies and help with the public health efforts,” Barford said. The stock market has not incorporated “enough analysis surrounding the politics of a vaccine and how even if the science delivers, our political leaders may fail the test by overly politicizing the process to a point that it will take longer than anticipated for a sufficient number of people to agree to be vaccinated to reach herd immunity in the U.S.,” according to Barford.

But the tone of U.S. regulators should put citizens at ease as it “suggests that regardless of political pressure, the FDA continues to apply sound regulatory judgment and expertise to the development of all medical products, particularly vaccines, regardless of the severity of the economic, political, or public health urgency of the current situation,” Porges said, “For that integrity, the general public, the biopharma industry, and all of its investors should be grateful.”

**LEGAL**

**Hospitals Lose Bid for Attorneys’ Fees in Medicare Bad Debt Case**

Seventy-five long-term hospitals that won a lawsuit in which they sought over $20 million in payments from the Centers for Medicare and Medicaid Services may not recover over $1.3 million in attorneys’ fees and litigation costs, a federal court in the District of Columbia said.

The Select Medical Corp. hospitals didn’t show CMS acted in bad faith before or during the litigation over their right to collect money to reimburse them for Medicare patients’ bad debts, the U.S. District Court for the District of Columbia said Thursday.

Additionally, CMS’ position in defending the policy challenged by the hospitals was substantially justified, the court said in denying their motion for attorneys’ fees and costs.
The hospitals sued CMS over its reimbursement policy for costs incurred in treating patients known as “dual eligibles” because they qualified for both Medicare and Medicaid coverage.

Specifically, they argued the agency violated federal law when it adopted a “must bill” policy that required them to bill state Medicaid agencies before submitting claims for Medicare coverage, even in states where the bills were sure to be denied because their Medicaid programs didn’t cover long-term care.

The district court ruled for the hospitals in August 2019. It said the agency erred by not submitting the policy to notice-and-comment rulemaking before adopting it because it changed a substantive legal standard. The court relied on the U.S. Supreme Court’s decision in *Azar v. Allina Health Servs.*, in determining that this was the type of policy change that required that procedure.


**Obamacare Backers See Hope in Roberts Opinion in Non-Health Case**

Chief Justice John Roberts may have assured advocates fighting to save Obamacare that he plans to save the law a second time. In striking down a provision of the Dodd-Frank Act that protected the director of the Consumer Financial Protection Bureau from being fired and leaving the agency intact, Roberts signaled Monday that he may do something similar with the Affordable Care Act—toss out its mandate to buy insurance without throwing out the entire law, health lawyers say.

The high court’s 5-4 ruling in *Seila Law LLC v. CFPB* has nothing to do with health care, but it asks the same question that’s central in the fight over former President Barack Obama’s signature health-care law: whether one unconstitutional provision sinks an entire statute. Dismantling the CFPB “would trigger a major regulatory disruption and would leave appreciable damage to Congress’s work in the consumer-finance arena,” Roberts said in delivering the majority decision. “Congress would prefer that we use a scalpel rather than a bulldozer in curing the constitutional defect we identify today,” he said.

The chief justice “went out of his way in the opinion to talk about the kind of regulatory disruptions that could occur with an overly aggressive approach to severability, said Abbe Gluck, a professor of law and the founding faculty director of the Solomon Center for Health Law and Policy at Yale Law School. “That kind of disruption is obviously a fundamental risk in the Affordable Care Act case,” she said.

The justices are expected next term to review a ruling from the U.S. Court of Appeals for the Fifth Circuit that left Obamacare in limbo. The appeals court ruled the ACA provision that requires everyone to buy health insurance or pay a penalty is unconstitutional. Because the 2017 Congress dropped the penalty to zero, the provision is no longer a valid exercise of Congress’s taxing power, the Fifth Circuit reasoned. Roberts had saved the law in 2012 by upholding the individual mandate as a constitutional tax on those who don’t have health insurance.

But the Fifth Circuit failed to answer a central question in this latest challenge: whether the rest of the law can survive without that one provision. As the country grapples with the coronavirus pandemic, the Justice Department told the Supreme Court in a June 25 brief the entire law must be thrown out. If the court sides with the Texas-led, Republican state coalition challenging the law, the Center for American Progress has estimated that 23 million people could lose their health insurance. Also at stake are dozens of other provisions, including protections for people with pre-existing conditions; requirements that insurers offer essential health benefits like preventative care, hospitalization and prescription drug coverage; the ability for parents to keep adult children on their plans until the age of 26; and the ability of states to expand their...
Medicaid programs. “I would be shocked if the chief justice endorses any of the arguments that Texas is making,” said Jonathan Adler, a law professor at the Case Western Reserve University School of Law.

The court’s ruling in Seila Law is further proof that Roberts isn’t interested in issuing decisions that are highly disruptive, Adler said. He noted the chief justice sided with the court’s liberal wing June 18 to save thousands of people who were brought to the country illegally as children from being deported. In the Seila Law case, “the court embraced the idea that you kick out as little as possible and presume Congress would have wanted more to survive than less,” Adler said. There’s more evidence of that in the Texas case than in this case against the CFPB, he added.

However, Obamacare challengers say Adler and others are misreading the high court’s ruling. “The inquiry is not as to the consequence of the ruling, it’s about the text of the statute itself,” said Robert Henneke, the general counsel for the Texas Public Policy Foundation, who’s representing the two individuals challenging the law alongside the GOP state coalition. This is the second indication in recent weeks of the court’s commitment to follow the statute, he said. “Let’s not forget the Bostock opinion from last week that soundly rejected legislative intent and extraneous consequences in saying no, the text is the text, is the text, is the text.”

In that decision June 15, Justice Neil Gorsuch and Roberts joined the court’s liberal wing in ruling that anti-discrimination protections in the workplace under Title VII of the Civil Rights Act extend to lesbian, gay, and transgender people. When it comes to Obamacare, the ACA was clear that the stated goal was universal insurance coverage and the requirement for individuals to purchase insurance was described by Congress as an essential way to achieve that goal, Henneke said.

There is another non-health-care case before the Supreme Court that asks the same question as the Seila Law and Obamacare case. In Barr v. American Association of Political Consultants Inc., the court is asked to review the constitutionality of an amendment to the Telephone Consumer Protection Act that exempts calls to collect government-owed debt. The justices may be able to resolve the case without having to reach the question of whether that amendment can be severed from the law if they rule it’s constitutional.

Class Certification Over Medicaid Repayments Reversed in Ohio

An Ohio trial court improperly considered claims by people who allegedly overpaid the state Medicaid agency to reimburse it for medical care they needed after being injured by other people, because state law provides an exclusive administrative remedy for them, the state’s top court said Tuesday.

The Ohio Supreme Court reversed certification of a class of Medicaid recipients who challenged the validity of a state law giving Ohio the right to automatically recover its Medicaid payments, saying the lower court lacked subject matter jurisdiction over the case.

The case relates to a complex issue in Medicaid, the joint federal-state health program. The Medicaid Act requires states to recover money paid for medical care required by a recipient due to injuries caused by a third party, whenever possible.

Ohio has a subrogation law setting out how and when it can seek repayment. The law used to say the state could collect the entire amount it spent from a judgment or settlement the recipient recovered from the third party.
But the state changed the law after the U.S. Supreme Court declared that a state may collect its payment only from the part of the judgment or settlement attributed to the recipient’s medical expenses. Ohio’s law allowed the state Medicaid agency to collect up to half the judgment or settlement or the whole of its payment, whichever was less.

The Supreme Court again weighed in on the issue, saying states may not create a conclusive presumption that a portion of a judgment or settlement represents medical costs. The Ohio legislature again changed its law, making the presumption rebuttable instead of conclusive, meaning the recipients could challenge its determination.

The new law also contained an administrative process for people to recover an alleged overpayment. The Ohio Supreme Court has now said that process is exclusive, at least for recipients who repaid the state before it made the presumption rebuttable.

The case is Pivonka v. Corcoran, Ohio, No. 2019-0084, 6/30/20.

AROUND THE STATES

Michigan

**Health Workers to Get Pay Bump Under Michigan Covid Relief Law**

Michigan health-care workers will see pay raises and day care centers will get cash grants to make up for shrinking class sizes under a sweeping $880 million coronavirus relief package signed into law Wednesday. The measure (S.B. 690) will distribute roughly one-third of the state’s $3.1 billion in CARES Act funding. The remainder will be allocated according to a deal struck by Michigan Gov. Gretchen Whitmer (D) and the General Assembly’s Republican leadership Monday night that seeks to patch a $2.2 billion budget hole the state faces.

“Between the signing of this bill today and the recent agreement on the 2020 budget announced earlier this week, we have now put the full amount of the federal Coronavirus Relief Fund to use so that Michiganders can reap the full benefit of our federal funding,” Whitmer said in a statement.

“Now, we need Congress to act later this month and provide additional aid to the states so that we can begin to address the budget shortfall in 2021,” she said.

The biggest portions of the bill’s funds will go toward local government grants meant to reimburse counties and municipalities for their virus response ($200 million); a stipend for child care facilities that have state-reduced class sizes ($125 million); $2-per-hour pay raises for state health-care workers ($120 million); bonus payments for local first responders ($100 million); and grants to help support small businesses ($100 million).

The rest of the funds will be used for a series of other programs, including increasing internet connectivity for low-income school-age children ($25 million); offsetting a moratorium on residential water shutoffs ($25 million); and hiring 500 more state workers to support the beleaguered unemployment insurance system ($29 million).
Whitmer previously faced criticism by GOP House lawmakers for having Michigan lag behind other states that had already distributed their federal CARES Act funding. She said in testimony in June that her office was still trying to work out a deal with Republicans.

New York

New York Opening Virus Testing to All Residents, Cuomo Says
New York state is opening testing to all residents as the number of positive coronavirus cases in more than half of the country continues to rise.

The state previously had limited testing to essential workers, nursing-home staff and those who had been exposed. But Governor Andrew Cuomo said at a virus briefing on Wednesday that it has increased testing capacity and all New Yorkers can and should be tested.

“Go get a test,” Cuomo said. “It doesn’t cost you anything. It doesn’t hurt.”

Since March, the state has tested 4 million of its approximately 19 million residents and has more than 750 testing sites, he said.

The announcement came as the number of hospitalizations totaled 879, the lowest five-day average since the pandemic began in March, Cuomo said. Virus-related deaths also remained low, with 11 fatalities Tuesday. But “dark clouds” are on the horizon, Cuomo said. “We are in the middle of a national crisis and we have to be careful.”

He said other states had reopened too soon, and he again criticized President Donald Trump. “He denied the reality of this situation from Day One,” Cuomo said. “And now the country is suffering because of the president.”

He urged Trump to “come clean,” admit the threat of the virus and send a message to the nation: “Put a mask on it, Mr. President.”

New York, New Jersey, and Connecticut on Tuesday expanded their quarantine list to 16 states -- requiring those traveling from areas with a high number of positive cases to isolate for 14 days.

Though the number of new cases in New York remains low, citizen compliance is dropping and local governments aren’t correcting it, Cuomo said. The state is going to create its own enforcement department to supplement local efforts to police social distancing, he said.

Oklahoma

Rural Hospitals Get Boost From Oklahoma Vote To Expand Medicaid
Oklahoma’s struggling rural hospitals could have better odds of staying open after voters narrowly said yes Tuesday to expanding Medicaid to cover at least 178,000 more adults.

A proposed amendment to the state Constitution (State Question 802) was adopted with 50.5% of the vote, according to unofficial returns posted on the state government’s website.
Approval of the measure means Oklahoma will join 35 other states and the District of Columbia in extending Medicaid to more people under Obamacare.

Expansion boosters say the program will provide desperately needed federal support for the state’s rural hospitals. “We certainly know that Medicaid expansion will give vulnerable hospitals a fighting chance, but we don’t have a crystal ball,” Susie Wallace, spokeswoman for the Oklahoma Hospital Association, said in an email before the vote. The association backed the Yes on 802 campaign.

A rural hospital’s likelihood of closure goes down by 62% if it’s located in a Medicaid expansion state, according to a 2019 study by the Chartis Center for Rural Health. Oklahoma’s eight rural hospital closures over the past decade are surpassed only by Texas and Tennessee, according to data compiled by by the Cecil G. Sheps Center at the University of North Carolina at Chapel Hill.

Voter approval starts the clock ticking for the Oklahoma Health Care Authority to prepare to accept new enrollments in the health care program no later than July 1, 2021. The state has 90 days to submit all documents to obtain federal signoff. Single adults with no dependents, who now aren’t covered at all, could sign up for Medicaid if they make less than $17,236 annually under the expansion.

Opponents of the measure, including Gov. Kevin Stitt (R), have long lamented about the state’s share of the cost of expansion, which according to Stitt could be about $200 million. After opposing Medicaid expansion, Stitt responded to the ballot measure with an effort to offer a narrower version by taking advantage of the Trump administration’s offer to convert Medicaid funding into a block grant. His plan included work requirements and monthly premiums for enrollees.

The legislature passed a hospital fee bill (SB 1046) that would have provided $134 million to pay for the state’s share of Stitt’s proposal, but he vetoed it. “I was surprised by the veto because so many constructive negotiations had occurred and stakeholders were on the same page,” Rep. Marcus McEntire (R), chairman of the Appropriations and Budget for Health Committee, said in a June 26 text message. “It looks like we will rehash and renegotiate during the next legislative session.” “I do not know of a legislator who looks forward to renegotiating how to pay for expansion or how care is managed for the expansion population,” he said.