The COVID-19 pandemic has created unprecedented challenges for healthcare providers and health insurers. The following is a selection of federal and state actions as well as news and analysis articles from the Health Policy Tracking Service as published in its bi-weekly Snapshots. The selection includes Regulatory Intelligence and Reuters news coverage. More COVID-19 news and information can be found via the TRRI platform’s search facility.

Additional COVID-19 resources are also available on the Thomson Reuters COVID-19 Resource Center. For a regularly updated list of U.S. state updates on insurance-sector regulatory changes related to the COVID-19 epidemic, please click on this link: http://go-ri.tr.com/fuaD4N. For an updated summary of federal legislation and regulations related to the pandemic, please click on this link to the Skopos Labs Coronavirus Policy Tracker: https://coronavirus.skoposlabs.com.

You can create your own custom My Updates through the Create a Custom My Updates link on the Regulatory Intelligence homepage. Select your geography and/or content types you would like resources from and include the following keyword search: covid! or coronavirus.

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1 This COVID-19 Coverage Snapshot was compiled by members of the publisher’s staff.
COVID-19 COVERAGE

COVID-19 LEGISLATIVE AND REGULATORY ACTIONS

Alaska
The Department of Professional Regulations has adopted regulation changes dealing with Expedited Handling of Prescriptions in Response to the COVID-19 Pandemic and Future Disasters. See 2020 AK REG TEXT 551498 (NS).

California
• 2019 CA S.B. 932 (NS), amended/substituted August 6, an act to add Section 120117 to the Health and Safety Code, relating to communicable diseases, and declaring the urgency thereof, to take effect immediately.
• 2019 CA S.B. 980 (NS), amended/substituted August 3, relating to genetic testing companies and privacy of COVID-19 testing.

Massachusetts
2019 MA H.B. 4916 (NS), introduced July 29, to promote resilience in our health care system.

New Jersey
• 2020 NJ S.B. 2790 (NS), introduced July 30, establishes certain requirements concerning State's preparedness and response to infectious disease outbreaks, including coronavirus disease 2019 (COVID-19) pandemic.
• 2020 NJ A.B. 4476 (NS), introduced July 30, establishes certain requirements concerning State's preparedness and response to infectious disease outbreaks, including coronavirus disease 2019 (COVID-19) pandemic.

New York
• 2020 NY S.B. 8835 (NS), approved and effective August 3, to amend the public health law, in relation to amending provisions regarding health care facilities and professionals during the COVID-19 emergency.
• 2019 NY S.B. 8869 (NS), introduced August 3, rules and regulations requiring nursing homes and residential health care facilities to test all residents of such nursing homes and residential healthcare facilities for the novel coronavirus (COVID-19).
• To ensure that all general hospitals maintain a 90-day supply of PPE during the COVID-19 emergency. See 2020 NY REG TEXT 561430 (NS).
• To allow telemedicine in some circumstances for social distancing purposes due to outbreak of COVID-19. See 2020 NY REG TEXT 561431 (NS).

Texas
The Executive Commissioner of the Health and Human Services Commission (HHSC) adopts on an emergency basis in Title 40 Texas Administrative Code, Chapter 30, Medicaid Hospice Program, an amendment to s.30.14(e), concerning an emergency rule in response to COVID-19 in order to allow face-to-face reassessments for recertification to be conducted as a telemedicine medical service. See 2020 TX REG TEXT 561243 (NS).

Utah
• This emergency rule filing supersedes the previous Filing No. 52797 that was effective 05/27/2020. The purpose of this change is to allow easier access to Medicaid services during the Coronavirus (COVID-19) Pandemic. See 2020 UT REG TEXT 561507 (NS).
• The purpose of this change is to allow certain income exclusions to help members of the Children's Health Insurance Program (CHIP) remain eligible during the Coronavirus (COVID-19) Pandemic. See 2020 UT REG TEXT 561529 (NS).

Washington
• The Health Care Authority is revising this section to allow for payment of office visits for clients under the alien emergency medical (AEM) program when the visit is specifically for the assessment and treatment of the COVID-19 virus. See 2020 WA REG TEXT 561687 (NS).
• The Health Care Authority is revising this section to temporarily eliminate the requirement for date and signature from the Medicaid client or the client's designee upon delivery of medical equipment and supplies. See 2020 WA REG TEXT 561691 (NS).
• The Health Care Authority's Medicaid disaster relief SPA 20-0014 was approved by the Centers for Medicare and Medicaid Services on April 24, 2020. This SPA implements policies and procedures that are different than those otherwise applied under the Medicaid state plan during the period of the presidential and secretarial emergency declarations related to the COVID-19 outbreak (or any renewals thereof). See 2020 WA REG TEXT 561709 (NS).
• In response to the current public health emergency surrounding the outbreak of the coronavirus disease (COVID-19), along with the governor of Washington's emergency proclamations related to COVID-19, the Health Care Authority (HCA) is creating these new rules to identify income that HCA does not count when determining apple health eligibility. See 2020 WA REG TEXT 561781 (NS).
• WAC 246-945-010, prescription labeling, records, and advertising-Minimum requirements, the Pharmacy Quality Assurance Commission is adopting emergency rules to reduce burdens on practitioners prescribing Schedule II substances during the coronavirus disease (COVID-19) outbreak. WAC 246-945-010 replaces WAC 246-887-010. This emergency rule will replace WSR 20-09-133. See 2020 WA REG TEXT 553783 (NS).

OTHER NEWS AND SUMMARIES

Utah Man Posing As Medical Doctor To Sell Baseless Coronavirus Cure Indicted On Fraud Charges
Utah resident Gordon H. Pedersen has been indicted for posing as a medical doctor to sell a baseless treatment for coronavirus (COVID-19). According to the indictment returned by a federal grand jury in Salt Lake City late last week, Pedersen fraudulently promoted and sold ingestible silver-based products as a cure for COVID-19 despite having no evidence that his products could treat or cure the disease. Pedersen is also alleged to have claimed to be a physician and worn a stethoscope and white lab coat in videos and photos posted on the Internet to further his alleged fraud scheme.

In a related matter, the company Pedersen previously co-owned, My Doctor Suggests LLC (My Doctor Suggests), has agreed to plead guilty to a one-count criminal information related to its false and misleading marketing of ingestible silver products as a drug treatment for COVID-19. The company has severed ties with Pedersen and agreed to cooperate in his prosecution. The criminal information filed Thursday in the U.S. District Court for the District of Utah are part of a global resolution with My Doctor Suggests that also includes a civil consent order requiring the company to cease fraudulently labeling its products and to issue full refunds to affected consumers.
“The Department of Justice will take swift action to protect consumers from those who offer phony cure-alls for the treatment and prevention of COVID-19,” said Acting Assistant Attorney General Ethan Davis. “We will continue to work closely with our partners at the Food and Drug Administration to quickly shut down schemes to promote and sell unlawful products during this pandemic.”

The indictment against Pedersen alleges that, beginning in early 2020, he conducted a scheme to defraud consumers throughout the United States, by falsely presenting himself as a medical doctor and promoting and selling silver products on the Internet based on fraudulent claims of protection against, and treatment for, COVID-19, in the midst of a worldwide pandemic.

According to the criminal information filed Friday, My Doctor Suggests made false and misleading claims that the company’s silver-based products could be ingested to protect against COVID-19 and the products lacked the necessary directions for use as a drug product. The information also allege My Doctor Suggests operated without properly registering with the Food and Drug Administration (FDA). It is anticipated My Doctor Suggests will plead guilty to a single misdemeanor count of distributing misbranded drug products in interstate commerce in violation of the Food, Drug, and Cosmetic Act.

The Department of Justice previously sought and obtained an emergency court order in the U.S. District Court for the District of Utah, alleging in its civil complaint that My Doctor Suggests worked with two co-defendants, Pedersen and his company GP Silver LLC, to fraudulently promote and sell various silver products for the treatment and prevention of COVID-19. Subsequent orders temporarily enjoined Pedersen, GP Silver LLC, and My Doctor Suggests from distributing silver products as well as representing they could cure, mitigate, treat, or otherwise prevent COVID-19 or any other disease. The recent consent order permanently enjoins My Doctor Suggests LLC from making these representations, and it provides a notification and refund process for deceived consumers.

The consent order specifically requires that My Doctor Suggests LLC permanently stop any fraudulent promotions, clearly and conspicuously disavow any statement that its silver products treat or prevent COVID-19 in future marketing materials and consumer notices, implement robust compliance measures to prevent a reoccurrence, and provide full refunds upon request to any customer who purchased its silver products under fraudulent pretenses. Affected customers can contact My Doctor Suggests LLC at (1-866-660-9868) or refunds@mydoctorsuggests.com.

REGULATORY INTELLIGENCE AND REUTERS NEWS

U.S. to Pay $2.1 billion to Sanofi, GSK, in COVID-19 Vaccine Deal
(Reuters) - The U.S. government will pay $2.1 billion to Sanofi SA and GlaxoSmithKline Plc for COVID-19 vaccines to cover 50 million people and to underwrite the drug makers’ testing and manufacturing, the companies said on Friday.²

The award is the biggest yet from ‘Operation Warp Speed’, the White House initiative aimed at accelerating access to vaccines and treatments to fight COVID-19, the respiratory disease caused by the novel coronavirus.

The deal, announced by the U.S. Department of Health and Human Services and Department of Defense, works out at a cost of around $42 per person inoculated.

That is almost identical to the $40 per patient the U.S. agreed to pay Pfizer Inc and BioNTech SE when it inked a nearly $2 billion deal for 50 million courses of that potential vaccine last week.

The Sanofi-GSK deal is for 100 million doses, at two per person, and gives the government an option to purchase an additional 500 million doses at an unspecified price. Sanofi and GSK plan to start clinical trials for the vaccine in September.

Sanofi executive Clement Lewin said the companies had not yet agreed with the government on a specific price for the additional doses.

GSK said in a statement that more than half of the total funding will go into further development of the vaccine, including clinical trials, with the remainder used for a manufacturing ramp-up and delivery of doses.

The two companies’ inoculation is combination of a vaccine based on Sanofi’s flu shots and a complementary technology from GSK called an adjuvant, designed to improve the vaccine’s potency.

Sanofi will receive the bulk of the proceeds from the deal.

It marks the second contract for the Franco-British pair’s vaccine candidate after they agreed earlier this week to supply 60 million doses to the British government.

Reuters reported last week that Pfizer’s deal was expected to set a pricing benchmark for future deals between drugmakers and governments.

Moderna Inc and Pfizer began two 30,000-subject trials of COVID-19 vaccines on Monday that could clear the way for regulatory approval and use by the end of 2020.

Long-term Complications of COVID-19 Signals Billions in Healthcare Costs Ahead

(Reuters) - Late in March, Laura Gross, 72, was recovering from gall bladder surgery in her Fort Lee, New Jersey, home when she became sick again.³

Her throat, head and eyes hurt, her muscles and joints ached and she felt like she was in a fog. Her diagnosis was COVID-19. Four months later, these symptoms remain.

Gross sees a primary care doctor and specialists including a cardiologist, pulmonologist, endocrinologist, neurologist, and gastroenterologist.

"I’ve had a headache since April. I’ve never stopped running a low-grade temperature,” she said.

Studies of COVID-19 patients keep uncovering new complications associated with the disease.

With mounting evidence that some COVID-19 survivors face months, or possibly years, of debilitating complications, healthcare experts are beginning to study possible long-term costs.

Bruce Lee of the City University of New York (CUNY) Public School of Health estimated that if 20% of the U.S. population contracts the virus, the one-year post-hospitalization costs would be at least $50 billion, before factoring in longer-term care for lingering health problems. Without a vaccine, if 80% of the population became infected, that cost would balloon to $204 billion.

Some countries hit hard by the new coronavirus - including the United States, Britain and Italy - are considering whether these long-term effects can be considered a "post-COVID syndrome," according to Reuters interviews with about a dozen doctors and health economists.

Some U.S. and Italian hospitals have created centers devoted to the care of these patients and are standardizing follow-up measures.

Britain’s Department of Health and the U.S. Centers for Disease Control and Prevention are each leading national studies of COVID-19’s long-term impacts. An international panel of doctors will suggest standards for mid- and long-term care of recovered patients to the World Health Organization (WHO) in August.

YEARS BEFORE THE COST IS KNOWN
More than 17 million people have been infected by the new coronavirus worldwide, about a quarter of them in the United States.

Healthcare experts say it will be years before the costs for those who have recovered can be fully calculated, not unlike the slow recognition of HIV, or the health impacts to first responders of the Sept. 11, 2001 attacks on the World Trade Center in New York.

They stem from COVID-19’s toll on multiple organs, including heart, lung and kidney damage that will likely require costly care, such as regular scans and ultrasounds, as well as neurological deficits that are not yet fully understood.

A JAMA Cardiology study found that in one group of COVID-19 patients in Germany aged 45 to 53, more than 75% suffered from heart inflammation, raising the possibility of future heart failure.

A Kidney International study found that over a third of COVID-19 patients in a New York medical system developed acute kidney injury, and nearly 15% required dialysis.

Dr. Marco Rizzi in Bergamo, Italy, an early epicenter of the pandemic, said the Giovanni XXIII Hospital has seen close to 600 COVID-19 patients for follow-up. About 30% have lung issues, 10% have neurological problems, 10% have heart issues and about 9% have lingering motor skill problems. He co-chairs the WHO panel that will recommend long-term follow-up for patients.

"On a global level, nobody knows how many will still need checks and treatment in three months, six months, a year,” Rizzi said, adding that even those with mild COVID-19 “may have consequences in the future.”
Milan’s San Raffaele Hospital has seen more than 1,000 COVID-19 patients for follow-up. While major cardiology problems there were few, about 30% to 40% of patients have neurological problems and at least half suffer from respiratory conditions, according to Dr. Moreno Tresoldi.

Some of these long-term effects have only recently emerged, too soon for health economists to study medical claims and make accurate estimates of costs.

In Britain and Italy, those costs would be borne by their respective governments, which have committed to funding COVID-19 treatments but have offered few details on how much may be needed.

In the United States, more than half of the population is covered by private health insurers, an industry that is just beginning to estimate the cost of COVID-19.

CUNY’s Lee estimated the average one-year cost of a U.S. COVID-19 patient after they have been discharged from the hospital at $4,000, largely due to the lingering issues from acute respiratory distress syndrome (ARDS), which affects some 40% of patients, and sepsis.

The estimate spans patients who had been hospitalized with moderate illness to the most severe cases, but does not include other potential complications, such as heart and kidney damage.

Even those who do not require hospitalization have average one-year costs after their initial illness of $1,000, Lee estimated.

‘HARD JUST TO GET UP’
Extra costs from lingering effects of COVID-19 could mean higher health insurance premiums in the United States. Some health plans have already raised 2021 premiums on comprehensive coverage by up to 8% due to COVID-19, according to the Kaiser Family Foundation.

Anne McKee, 61, a retired psychologist who lives in Knoxville, Tennessee and Atlanta, had multiple sclerosis and asthma when she became infected nearly five months ago. She is still struggling to catch her breath.

“On good days, I can do a couple loads of laundry, but the last several days, it’s been hard just to get up and get a drink from the kitchen,” she said.

She has spent more than $5,000 on appointments, tests and prescription drugs during that time. Her insurance has paid more than $15,000 including $240 for a telehealth appointment and $455 for a lung scan.

“Many of the issues that arise from having a severe contraction of a disease could be 3, 5, 20 years down the road,” said Dale Hall, Managing Director of Research with the Society of Actuaries.

To understand the costs, U.S. actuaries compare insurance records of coronavirus patients against people with a similar health profile but no COVID-19, and follow them for years.

The United Kingdom aims to track the health of 10,000 hospitalized COVID-19 patients over the first 12 months after being discharged and potentially as long as 25 years. Scientists
running the study see the potential for defining a long-term COVID-19 syndrome, as they found with Ebola survivors in Africa.

“Many people, we believe will have scarring in the lungs and fatigue ... and perhaps vascular damage to the brain, perhaps, psychological distress as well,” said Professor Calum Semple from the University of Liverpool.

Margaret O’Hara, 50, who works at a Birmingham hospital is one of many COVID-19 patients who will not be included in the study because she had mild symptoms and was not hospitalized. But recurring health issues, including extreme shortness of breath, has kept her out of work.

O’Hara worries patients like her are not going to be included in the country’s long-term cost planning.

“We’re going to need ... expensive follow-up for quite a long time,” she said.

**Trump Signs Executive Order to Expand Telehealth Use Beyond COVID-19 Emergency**

(Regulatory Intelligence) - President Donald Trump moved to expand telehealth, especially in rural areas, by easing regulation and updating rules over federal health payments related to its use even after the COVID-19 emergency ends.4

The changes being planned for the federal-government run Medicare program may set a precedent for private insurers offering Medicare supplemental plans, Medicaid, and individual market plans.

“I am taking action to make sure telehealth is here to stay,” Trump said at a press briefing late Monday.

Though the concept of virtual care has existed for over two decades, telehealth’s popularity skyrocketed in March as healthcare providers and consumers soaked up the convenience and accessibility when widespread stay-at-home orders as a result of the COVID-19 outbreak disrupted routine healthcare visits.

Trump on Monday ordered the Centers for Medicare & Medicaid Services (CMS) to propose a rule to extend parts of Medicare’s broader coverage of telehealth at no cost, beyond the ongoing public health emergency. The order also directs the CMS to propose a payment model to improve rural access to healthcare.

The U.S. Department of Health and Human Services is tasked with launching a rural health action plan which will include developing healthcare models for rural communities that focus on preventing disease and mortality by using technology and increasing access to care.

"The new gold standard for healthcare will be patients and providers deciding on the right blend of in-person and virtual care, when and where it makes sense for them,” HHS Secretary Alex Azar said in a statement.

The executive order also contains provisions to increase broadband access in rural areas to fully avail telehealth facilities.

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4 Antonita Madonna, Trump signs executive order to expand telehealth use beyond COVID-19 emergency, Thomson Reuters Regulatory Intelligence (August 4, 2020) at: http://go-ri.tr.com/x5CyDj.
About 1.7 million people were receiving virtual services through Medicare by the end of April, compared to only 14,000 beneficiaries who availed of these services prior to the start of the public health emergency in mid-March.

“The telehealth genie is not going back into the bottle”, CMS Administrator Seema Verma said.

HHS BRUSHES ASIDE OVERUTILIZATION CONCERNS
Worry about telehealth overutilization driving up costs should not be a barrier to its expanded adoption, Azar said in an newspaper opinion article on Saturday, playing down one of the biggest concerns expressed by insurers, who were wary of telehealth prior to the public health emergency caused by the pandemic.

“There’s a reluctance to let Medicare pay for more telehealth on the grounds that this will drive up healthcare utilization, straining our healthcare system and the program’s budget. That kind of static thinking is one of the biggest problems in American healthcare,” he wrote.

Azar said regulations and other barriers to accessing convenient care must be removed especially at a time when the healthcare system is seeing a shift to paying for better health outcomes rather than procedures. "We can safely protect privacy while fixing regulations so that they don’t stand in the way of coordinated, patient-centered care”, he said.

CMS had dramatically expanded Medicare coverage for telehealth in March, at the start of the COVID-19 outbreak in the United States. Data from the last few months will drive regulatory reforms, Azar said. “In many cases, Congress needs to make statutory changes, and we’re working with members of both parties on that already,” Azar wrote.

Health insurers have long been reluctant to cover telehealth services as concerns of overutilization, fraud, privacy breaches, and limitations over physicians’ licensing boundaries. At the start of the pandemic, however, insurers quickly broadened their coverage of telehealth consultations to reimburse consultations over the phone or video calls at the same rate as face-to-face visits with healthcare providers, in line with the CMS’ modified rules on Medicare.

The future of the astronomical growth seen in telehealth is largely expected to depend on insurers’ continued support of reimbursement for telehealth use.

U.S. Health Insurers Cite Government-plan Enrollment Gains in Second Quarter
(Regulatory Intelligence) - Higher enrollment in the government-funded Medicaid program buoyed health insurers in the second quarter as regulatory relief and job losses made more consumers eligible for insurance coverage during the COVID-19 pandemic.5

Humana, Anthem and CVS Health, through its recent purchase of Aetna, recorded gains in Medicaid membership during the latest quarter largely due to states suspending their re-verification efforts and in some cases, widening eligibility criteria for sign-ups on the Medicaid program.

5 Antonita Madonna, U.S. health insurers cite government-plan enrollment gains in second quarter, Thomson Reuters Regulatory Intelligence (August 6, 2020) at: http://go-ri.tr.com/nJkf1K.
“We continue to view Medicaid as a focus area with a strong pipeline of opportunities headed into 2021,” Eva Boratto, chief financial officer at CVS said on a conference call on Wednesday. The company’s Medicaid membership grew 4.9 percent sequentially in the second quarter.

Humana clocked a 47 percent increase in Medicaid membership, or about 220,000 additional customers, in the first half of this year as a result of new enrollments and new contracts in some states. The company also said it expects to grow its full-year Medicare Advantage membership to a range of between 330,000 to 360,000 this year from its previous range of 300,000 to 350,000 for the same period.

Besides, health insurers are also benefiting from lower-than-expected loss of members in commercial plans as many employers chose to furlough their workers with continued health coverage instead of terminating their employment completely.

Anthem, which operates in the commercial and government-aided health coverage segments, said its second-quarter Medicaid enrollment grew sequentially by nearly 10 times the decline it saw in its employer group enrollment.

Cigna, which largely operates through commercial plans, saw its membership remain flat in the second quarter from a year ago, despite widespread unemployment in the United States since the start of the pandemic that has forced more than 50 million to file for jobless claims.

CVS said its commercial membership declined approximately 0.5 percent sequentially, reflecting the impact of unemployment.

DEFERRED CARE MAY RETURN SOON
Health insurers largely reported care utilization reaching near-normal levels at the end of the second quarter, leading to expectations of a return of deferred care and higher claims costs in the second half of the year.

The new spike in COVID-19 infections in the southern part of the country, however, has led to new uncertainty over the trend continuing to pick up at the same pace through the rest of the year.

“There is another spike in COVID here in July. We’re actually monitoring it very closely, trying to understand what the impact of the deferrals are and how the pent-up demand is impacting as well”, said John Gallina, Anthem’s chief financial officer said on a conference call last week.

“We have seen an increase in procedures, such as joint replacement surgeries and other procedures, some things can only be delayed so long until the pain or the severity is so significant that the person is going to go in and actually get the procedure”, he added.

Stay-at-home orders in March and April and cancellations of elective medical procedures to free up hospitals and healthcare staff to tend to COVID-19 patients had led to lower claims cost for insurers through the first half of 2020. While insurers are preparing for a higher-than-usual number of claims in the second half of the year from deferred care, uncertainty remains over the severity of the claims as care delays may have led to more chronic health conditions.