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 April 20 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.
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COVID-19 COVERAGE

COVID-19 LEGISLATIVE AND REGULATORY ACTIONS

FEDERAL ACTIONS

• 2019 CONG US HR 6511, introduced April 14, to amend titles XIX and XXI of the Social Security Act to require coverage under the Medicaid program and Children's Health Insurance Program for vaccines and treatment for COVID-19 without the imposition of cost sharing requirements, and for other purposes.

• 2019 CONG US S 3517 seeks to increase access to Medicare and Medicaid telehealth services in nursing homes during the COVID-19 emergency. Among other things, the bill would direct the Secretary of the Department of Health and Human Services to identify barriers to nursing homes’ ability to access telehealth during the emergency. It would also allow the secretary to make emergency grants to nursing homes to allow residents to have virtual visits with their loved ones and others during the COVID-19 emergency period. The bill, which was introduced on March 18, 2020, is sponsored by Senators Amy Klobuchar (D-Minn.) and Bob Casey (D-Pa.).

• 2019 CONG US S 3544 would enact the Coronavirus Relief for Seniors and People with Disabilities Act of 2020. The bill is broadly aimed at keeping seniors safe and healthy during the COVID-19 pandemic. As it relates to Medicaid, the bill would award Medicaid grants to the states to ensure that seniors and those with disabilities have needed access to home- and community-based services. A document from the Committee on Aging explains how the bill could help accomplish that: Through Medicaid grants to States, the bill would provide funding to ensure that seniors and people with disabilities who need care at home can receive it. States need these additional, new dollars to minimize waiting lists for home and community-based services and to provide wage increases as well as overtime pay and paid sick, medical and family leave to home health workers.2

STATE ACTIONS

Alaska

- **2019 AK S.B. 241** (NS), adopted April 9, extending the March 11, 2020, governor's declaration of a public health disaster emergency in response to the novel coronavirus disease (COVID-19) pandemic; providing for a financing plan; making temporary changes to state law in response to the COVID-19 outbreak in the following areas: standing orders of the chief medical officer; occupational and professional licensing, practice, and billing; telehealth; fingerprinting requirements for health care providers; elections in calendar year 2020; permanent fund dividend applications and eligibility; state tax filings, payments, and related provisions.

- The Board of Nursing proposes to update regulation changes made by emergency regulation regarding courtesy license. On April 6, 2020, the Alaska Board of Nursing adopted, as an emergency regulation, changes in 12 AAC 44.318 of the Alaska Administrative Code dealing with courtesy license, including the following: 12 AAC 44.318. Courtesy license, is proposed to be amended to allow successful LPN, RN, and APRN applicants that meet the specific requirements for emergency courtesy licensure during this public health emergency caused by COVID-19 pandemic. The emergency regulation took effect on April 10, 2020, and will expire August 7, 2020. The Alaska Board of Nursing does not intend to make the emergency regulation permanent. See [2020 AK REG TEXT 551955](#) (NS).

Colorado

The purpose of this emergency regulation is to establish the coverage and cost-sharing requirements for commercial insurance carriers related to claims arising from the testing and treatment of COVID-19. See [2020 CO REG TEXT 551979](#) (NS).

Florida

The proposed emergency rule allows for a continuation of services to Florida's mental health care recipients of registered interns which will likely be interrupted due to risk of transmittal of COVID-19 during the present health care emergency as registered interns are not currently able to provide services via remote electronic methods. See [2020 FL REG TEXT 551383](#) (NS).

Georgia

This executive order provides that the Georgia State Board of Pharmacy is authorized and directed to implement the suspension of O.C.G.A. s. 26-4-82(c)(2) and Ga. Comp. R. & Regs. r. 480-15-.03(d)(2), to the extent necessary to allow pharmacy technicians and pharmacists to complete computer-based processing of prescriptions at alternative locations, including from the residence of the pharmacy technician or pharmacist. See [2020 GA REG TEXT 551612](#) (NS).

Illinois

- This proposed amendment significantly broadens telehealth rules to accommodate new places of service and means of engagement and communication during the COVID-19 public health emergency. See [2020 IL REG TEXT 551442](#) (NS).

- During the duration of the Gubernatorial Disaster Proclamation, the provisions in the Healthcare Worker Background Check Act, 225 ILCS 46/33(g), that prohibit an individual from being hired to work as a certified nursing assistant if they have been inactive on the Health Care Worker Registry are suspended if the individual (1) has been in inactive status for a period of no more than 5 years, (2) was in good standing at the time they became inactive, and (3) completes and submits any forms required by the Department of Public Health. See [2020 IL REG TEXT 551878](#) (NS).
Kentucky
2020 KY H.B. 387 (NS), enrolled April 15, relating to the rural hospital operations and facilities revolving loan fund, making an appropriation therefor, and declaring an emergency.

Louisiana
The aim of this Emergency Rule is to temporarily add additional codes for the purpose of delivering care and allowing providers to use telemedicine/telehealth methods. The Emergency Rule addresses the statewide public health emergency declared to exist in the state of Louisiana as the result of the imminent threat posed to Louisiana citizens by COVID-19, creating emergency conditions threatening the lives and health of the citizens of this state. See 2020 LA REG TEXT 551390 (NS).

Massachusetts
- Pursuant to 101 CMR 320.01(3), the Executive Office of Health and Human Services is adding a new procedure code for clinical laboratory services covering diagnostic tests for the 2019 novel Coronavirus (COVID-19). As set forth in 101 CMR 320.01(3)(c), rates for newly added codes are calculated according to the rate methodology used in setting clinical laboratory rates. Added codes without Medicare fees are reimbursed at individual consideration (I.C.). See 2020 MA REG TEXT 551526.
- 2019 MA H.D. 5016 (NS), draft/request April 7, relative to long-term care facility and elder housing COVID-19 reporting.
- 2019 MA S.B. 2630 (NS), introduced April 9, to provide liability protections for health care workers and facilities during the COVID-19 Pandemic.
- 2019 MA S.B. 2635 (NS), introduced April 15, to provide liability protections for health care workers and facilities during the COVID-19 Pandemic.
- 2019 MA H.B. 4635 (NS), draft/request April 7, 2020, provides for the reporting of COVID-19 positive cases and mortalities at assisted living residences, elderly housing facilities, and long-term care facilities.

Minnesota
- 2019 MN S.F. 4334 (NS), adopted March 17, prohibits a health carrier from excluding or reducing coverage for a health care service or consultation solely because the service or consultation is provided via telemedicine at the patient's residence.
- 2019 MN H.F. 4545 (NS), introduced April 14, to create an Immunity defense created for manufacturers producing COVID-19 products.
- Emergency Executive Order 20-28: allowing out-of-state mental health providers to render telehealth aid and permitting certain licensing boards to provide license and registration relief during the COVID-19 peacetime emergency. See 2020 MN REG TEXT 551971 (NS).
- Emergency Executive Order 20-32: ensuring that healthcare providers can respond quickly and safely during the COVID-19 peacetime emergency. See 2020 MN REG TEXT 551974 (NS).
- 2019 MN S.F. 4478 (NS), introduced April 16, to authorize telemedicine examination of patient by prescribing practitioner before issuing prescription drug for medication assisted therapy for treatment of substance abuse disorder.

New Jersey
- 2020 NJ A.B. 3943 (NS), introduced April 9, requires hospitals to report COVID-19 demographic data.
- 2020 NJ S.B. 2357 (NS), introduced April 9, requires hospitals to report COVID-19 demographic data.
• **2020 NJ A.B. 3906** (NS), introduced April 9, requires the state to lease hotel facilities as isolation centers for COVID-19 emergency.

• **2020 NJ A.B. 3910** (NS), amended/substituted April 13, provides civil and criminal immunity to certain health care professionals and health care facilities during public health emergency and state of emergency; facilitates issuance of certain temporary licenses and certifications during public health emergency and state of emergency.

• **2020 NJ A.B. 3953** (NS), introduced April 13, requires hospitals to report coronavirus disease 2019 demographic data.

• **2020 NJ S.B. 2333** (NS), adopted April 14, provides civil and criminal immunity to certain health care professionals and health care facilities during public health emergency and state of emergency; facilitates issuance of certain temporary licenses and certifications during public health emergency.

New York

• **2019 NY S.B. 8171** (NS), introduced April 13, would extend the provisions under section 3000-a of the public health law shall be extended to any individual or non-profit organization who voluntarily and without expectation of monetary compensation renders first aid or emergency treatment to an individual who is suffering and/or has been infected with coronavirus disease 2019 (COVID-19).

• **2019 NY S.B. 8182** (NS), introduced April 13, relates to authorizing licensed pharmacists to administer an approved vaccine for COVID-19.

• **2019 NY A.B. 10303** (NS), introduced April 15, relates to paratransit services within the state and city of New York during the coronavirus disease 2019 (COVID-19) pandemic.

• **2019 NY A.B. 10301** (NS), introduced April 15, relates to allowing prescriptions for controlled substances to be issued for greater than a thirty-day supply during a state of emergency.

Ohio

• **2019 OH H.B. 600** (NS), introduced April 6, to authorize a person who has had a valid commercial driver's license to drive an ambulance during the state of emergency due to COVID-19 and to declare an emergency.

• **2019 OH H.B. 598** (NS), introduced April 6, to temporarily authorize emergency medical technicians to perform certain medical services in hospitals and to declare an emergency.

• **2019 OH H.B. 606** (NS), introduced April 10, to grant civil immunity to a person who provides services for essential businesses and operations for injury, death, or loss that was caused by the transmission of COVID-19 during the period of emergency declared by Executive Order 2020-01D, issued on March 9, 2020, and to declare an emergency.

Oregon

• This temporary rule requires laboratories to report both positive and negative tests for COVID-19. Explicitly making COVID-19 hospitalizations and deaths reportable will allow public health officials to assess trends in severe illness and the fatality rate of the disease; and the effectiveness of social distancing measures. Health care providers must submit reports through an electronic case reporting portal. See **2020 OR REG TEXT 550935** (NS).

• On March 8, 2020 Governor Brown declared a public health emergency in Oregon related to the coronavirus pandemic (COVID-19). Whereas, during a declared emergency, the Board (or the Executive Director acting on behalf of the Board pursuant to OAR 855-007-0040) may adopt a temporary emergency rule as a way to address regulations impacting the health, safety and welfare of Oregonians. Chloroquine is effective for malaria treatment and prophylaxis, and hydroxychloroquine is effective for treatment of
rheumatoid arthritis, systemic lupus erythematosus and porphyria cutanea tarda. See 2020 OR REG TEXT 550880 (NS).

- The Division needs to amend this rule to support appropriate response during the COVID-19 crisis to ensure critical access to physical and behavioral health services via telehealth so that OHP members are not unnecessarily exposed to the COVID-19 virus. See 2020 OR REG TEXT 550903 (NS).

- In response to the COVID-19 global pandemic and resulting social distancing initiatives, the Board determined that there was an immediate need to provide an expedited means of licensure in Oregon for those who hold a license in good standing to practice as a professional counselor or as a marriage and family therapist in any state or the District of Columbia. See 2020 OR REG TEXT 550872 (NS).

- In response to the COVID-19 global pandemic, and resulting social distancing initiatives, the Oregon Board of Psychology determined that there is an immediate need to provide an additional limited permit type that is more expedited and provides a broader scope of work than the currently available Visitor’s Permit in that it allows services to be delivered to an unlimited number of clients. The Visitor’s Permit only allows for 30 days of practice within a 12 month period, which may not be sufficient for some practitioners to provide continuity of care to Oregonians who have been displaced due to the coronavirus. See 2020 OR REG TEXT 550917 (NS).

- Temporary rules are needed to increase payment for certain digital services and telephone visits between workers and their health care providers, and promote communication about the progress of recovery, when in-person care or telemedicine (two-way video) services are not possible or are unavailable. The Oregon Health Authority has recommended that reimbursement rates for telehealth services mirror payment rates for equivalent office visits. See 2020 OR REG TEXT 550940 (NS).

- Due to the COVID-19 state of emergency, the Department was asked by the COVID-19 Hospital Task Force to develop a plan to increase access to ventilator assisted services in nursing facilities. The Department is amending OAR chapter 411, division 70 to attempt to increase access to ventilator services, within the state, by working with nursing facilities on a rate that would be sustainable. See 2020 OR REG TEXT 550862 (NS).

- Based upon the needs of the community and health care systems, the temporary rule is needed to provide flexibility in the scope of practice for emergency medical services (EMS) providers during the period of the COVID-19 declared emergency. The temporary rule upholds the Oregon Medical Board’s mission to protect the health, safety, and wellbeing of Oregon citizens by only allowing this flexibility under a supervising physician’s standing orders and within the protocols established by the State of Oregon EMS Medical Director. See 2020 OR REG TEXT 550929 (NS).

- The Division needs to amend this rule to ensure telehealth services are reimbursable to IHS/FQHC/RHC providers. See 2020 OR REG TEXT 550899 (NS).

- Expired Oregon clinical social workers may be able to serve Oregon citizens during the period of the Governor’s Emergency Declaration dated March 8, 2020 in response to the COVID 19 situation. This will allow more Oregonians to receive mental health services during this emergency. See 2020 OR REG TEXT 550874 (NS).

- In response to the COVID-19 global pandemic, and resulting social distancing initiatives, the Board determined that there is an immediate need to temporarily allow licensees who are due to renew their licenses in the upcoming months to complete all of their continuing education via home study (online programs). See 2020 OR REG TEXT 550916.

- The temporary rule is needed to increase the potential number of respiratory therapists who can care for patients in Oregon during a declared emergency. The temporary rule meets that need by providing a streamlined provisional authorization process for respiratory therapists who meet certain criteria during a declared emergency. See 2020 OR REG TEXT 550914 (NS).
• The temporary rule is needed to increase the potential number of physicians and physician assistants who can care for patients in Oregon during a declared emergency. The temporary rule meets that need by reducing practice restrictions and providing a streamlined reactivation process for a qualified group of physicians and physician assistants during a declared emergency. See 2020 OR REG TEXT 550928.

• Clinical social workers appropriately licensed in another state of province may be able to serve Oregon citizens during the period of the Governor's Emergency Declaration dated March 8, 2020 in response to the COVID19 situation. This will allow Oregonians to continue to receive mental health services during this emergency. See 2020 OR REG TEXT 550873 (NS).

Rhode Island
• The Department of Human Services is waiving some requirements during the Novel Corona Virus crisis and the National Declaration of Emergency, to protect the health of the DHS applicants, recipients, and Department employees. See 2020 RI REG TEXT 550833 (NS).

• The Department of Human Services will waive some requirements for access to benefits for applicants and recipients during COVID 19-crisis and the Declaration of Emergency. See 2020 RI REG TEXT 550832 (NS).

• The Department of Human Services is waiving some requirements during the Novel Corona crisis and the National Declaration of Emergency, to protect the health of DHS applicants, recipients, child care providers, and DHS staff. See 2020 RI REG TEXT 550834.

South Carolina
2019 SC H.B. 5452 (NS), introduced April 8, to amend add section 44-29-260 to require the Department of Health and Environmental Control to ensure testing prioritization for first responders who present with symptoms of COVID-19.

Texas
• The Executive Commissioner of the Texas Health and Human Services Commission (HHSC) adopts on an emergency basis new s.500.1, Hospital Off-Site Facilities in Response to COVID-19, in Title 26, Texas Administrative Code, Chapter 500, concerning an emergency rule to allow hospitals to treat and house patients more effectively in response to COVID-19. See 2020 TX REG TEXT 551203 (NS).

• Amends 22 TX ADC § 187.57 (Charge of the Disciplinary Panel) modifying the definition for "continuing threat to the public welfare" to include a physician's performance of a non-urgent elective surgery or procedure. Provides for the postponement of all surgeries and procedures that are not immediately medically necessary to correct a serious medical condition or preserve a patient's life. Adds an exception for procedures that would not deplete hospital capacity or personal protective equipment needed to cope with the COVID-19 emergency. See 2020 TX REG TEXT 551201 (NS).

• Executive order that requires all licensed health care professionals and all licensed health care facilities shall postpone all surgeries and procedures that are not immediately medically necessary to correct a serious medical condition of, or to preserve the life of, a patient who without immediate performance of the surgery or procedure would be at risk for serious adverse medical consequences or death, as determined by the patient's physician; PROVIDED, however, that this prohibition shall not apply to any procedure that, if performed in accordance with the commonly accepted standard of clinical practice, would not deplete the hospital capacity or the personal protective equipment needed to cope with the COVID-19 disaster. Effective until 11:59 p.m. on April 21, 2020. See 2020 TX REG TEXT 551244 (NS).
• Executive order requiring all hospitals licensed under Chapter 241 of the Texas Health and Safety Code, and all Texas state-run hospitals, except for psychiatric hospitals, shall submit to DSHS daily reports of hospital bed capacity, in the manner prescribed by DSHS. DSHS shall promptly share this information with the CDC. See 2020 TX REG TEXT 551245 (NS).

• The Texas State Board of Pharmacy adopts on an emergency basis new rule s.291.30, concerning Medication Limitations, and finds that it is not practical to provide the usual 30 days’ prior notice and hearing. The Texas State Board of Pharmacy recognizes the extraordinary demand for chloroquine, hydroxychloroquine, mefloquine, or azithromycin as a result of COVID-19 (coronavirus). See 2020 TX REG TEXT 551202 (NS).

• The Executive Commissioner of the Texas Health and Human Services Commission (HHSC) adopts on an emergency basis new s.500.1, Hospital Off-Site Facilities in Response to COVID-19, in Title 26, Texas Administrative Code, Chapter 500, concerning an emergency rule to allow hospitals to treat and house patients more effectively in response to COVID-19. See 2020 TX REG TEXT 551203 (NS).

• The Texas Medical Board (Board) adopts on an emergency basis the emergency amendment to 22 TAC s.178.4(d) for purposes of the COVID-19 disaster declaration. The amendment is being made pursuant to Executive Order GA 09 and amends certain reporting requirements under 22 TAC s.178.4(d) for instances of physicians undertaking and performing non-urgent elective surgeries or procedures. See 2020 TX REG TEXT 551200 (NS).

Virginia
The Commonwealth of Virginia anticipates a sudden, yet temporary need to increase bed capacity in general hospitals and nursing homes within the Commonwealth. The increase may be needed to serve persons who become acutely ill due to the outbreak of a respiratory illness referred to as the novel coronavirus (COVID-19). Based on information from the Virginia Department of Health and the Centers for Disease Control and Prevention, the number of cases of COVID-19 continues to increase within the Commonwealth and in neighboring states. See 2020 VA REG TEXT 551903 (NS).

Washington
• 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 552046 (NS).

• The Health Care Authority is temporarily removing the requirement to obtain a signature from the Medicaid client or the client's designee upon receipt of pharmacy products dispensed and delivered directly to a client. See 2020 WA REG TEXT 552072 (NS).

• The Washington state department of health is waiving certain nursing fees that impose barriers to recruiting nurses who have inactive licenses or expired licenses for three years or less. See 2020 WA REG TEXT 552097 (NS).

• The department is enacting WAC 388-845-2019 on an emergency basis to make temporary modifications to the developmental disabilities administration’s home and community based services waivers in order to control the spread of the COVID-19 virus and to meet immediate health and safety needs. See 2020 WA REG TEXT 552057 (NS).

• The health care authority (HCA) in conjunction with the aging and long-term support administration (ALTSAs) within the department of social and health services (DSHS), intends to submit Medicaid SPA 20-0016 in order to include an add-on payment to the Medicaid rate for nursing facilities. See 2020 WA REG TEXT 552092 (NS).

• The purpose of this rule is to amend existing rules affecting specific programs as a result of the health crisis created by the coronavirus. See 2020 WA REG TEXT 552043 (NS).
• The health care authority (HCA) intends to submit Medicaid SPA 20-0014 to implement policies and procedures that may be different from the policies and procedures otherwise applied under the Medicaid state plan, during the period of the presidential and secretarial emergency declarations related to the COVID-19 outbreak. See 2020 WA REG TEXT 552095 (NS).

Wisconsin
• 2019 WI A.B. 1038 (NS) and 2019 WI S.B. 932 (NS), introduced April 13, 2020, would, for the duration of the public health emergency relating to COVID-19, allow the use in nursing homes of physician extenders in place of medical directors and attending physicians and telehealth options; waive notice of transfers within a nursing home due to medically necessary protection from COVID-19; waive requirements to document sufficient preparation and orientation to residents to ensure a safer and orderly intrafacility nursing home transfer; waive requirements for a nursing home bedhold policy; waive the requirements for nursing home in-service education under 42 CFR 483.35(d)(7); waive nurse staffing information and posting of that information for nursing homes; suspend the requirement that a pharmacist go monthly to the nursing home to do record review; waive or lessen requirements for a paid feeding assistant program in nursing homes and setting guidelines for training to assist with the COVID-19 pandemic; waive the annual and quarterly screening of fire extinguishers and any other annual maintenance review for nursing homes; waive life safety codes for nursing homes and other health care facilities relating to fire alarm system maintenance and testing, automatic sprinkler and standpipe system inspection, testing, and maintenance, and inspection and maintenance of portable fire extinguishers; allow home and community-based waiver services and administrative requirements to be provided remotely where possible.

• 2019 WI S.B. 932 (NS) was introduced April 13, 2020. The proposed bill is the state government response to the COVID-19 pandemic. The proposed bill includes provisions waiving requirements for managed care organizations to complete initial and periodic recredentialing of network providers if the providers meet Medical Assistance provider enrollment requirements during the 2019 novel coronavirus public health emergency. The proposed bill also seeks to require managed care organizations to extend preexisting authorizations through which a Medical Assistance recipient has received prior authorization until the termination of the 2019 novel coronavirus public health emergency.

FEDERAL ADMINISTRATIVE ACTIONS

CMS Issues Temporary Part D Regulatory Waivers and New Rules to Ensure Flexibility for Part D Enrollees During COVID-19 Pandemic
The Trump Administration has issued several temporary regulatory waivers and new rules intended to equip the American healthcare system with “maximum flexibility to respond to the 2019 Novel Coronavirus (COVID-19) pandemic.”

These temporary changes, which were made possible by President Trump’s recent emergency declaration and emergency rule making, will apply immediately across the entire U.S. healthcare system for the duration of the emergency declaration.

The goals of these actions are to:
• Ensure that local hospitals and health systems have the capacity to handle a potential surge of COVID-19 patients through temporary expansion sites (also known as CMS Hospital Without Walls);
• Remove barriers for physicians, nurses, and other clinicians to be readily hired from the community or from other states so the healthcare system can rapidly expand its workforce;
• Increase access to telehealth in Medicare to ensure patients have access to physicians and other clinicians while keeping patients safe at home;
• Expand in-place testing to allow for more testing at home or in community-based settings; and
• Put Patients Over Paperwork to give temporary relief from many paperwork, reporting and audit requirements so providers, health care facilities, Medicare Advantage and Part D plans, and States can focus on providing needed care to Medicare and Medicaid beneficiaries affected by COVID-19.

As part of the “Patients Over Paperwork” program, Part D plan sponsors may relax their “refill-too-soon” edits if circumstances are reasonably expected to result in a disruption in access to drugs. Part D sponsors may also allow an affected enrollee to obtain the maximum extended day supply available under their plan, if requested and available.

Also, in situations when a disaster or emergency makes it difficult for enrollees to get to a retail pharmacy, or enrollees are actually prohibited from going to a retail pharmacy (e.g., in a quarantine situation), Part D sponsors are permitted to voluntarily relax any plan-imposed policies that may discourage certain methods of delivery, such as mail or home delivery, for retail pharmacies that choose to offer these delivery services in these instances.

CMS is also pausing much of its standard medical review activities, including prior authorization and other reviews that require it to ask providers for documentation. In addition, CMS is reprioritizing scheduled program audits and contract-level Risk Adjustment Data Validation audits for MA organizations, Part D sponsors, Medicare-Medicaid Plans, and Programs of All-Inclusive Care for the Elderly organizations. Reprioritizing these audit activities is intended to allow providers, CMS, and the organizations to focus on patient care.

Relating to Medicare Advantage (Part C) and Part D Star Ratings, CMS states that it “is committed to allowing health plans, providers, and physician offices to focus on caring for Medicare beneficiaries during this public health emergency and not put individuals at risk by requiring travel or collection of data in offices that may be overwhelmed by patients needing care.” As such, the rule removes the requirement for Medicare health plans to submit Healthcare Effectiveness Data and Information Set (HEDIS) 2020 data covering the 2019 measurement year for the Medicare program. Medicare health plans can use any HEDIS data that they have collected for their internal quality improvement efforts.

CMS is removing the requirement for submission of 2020 Consumer Assessment of Healthcare Providers & Systems (CAHPS) survey data for Medicare health and drug plans for similar concerns about the potential associated with activities to collect and submit the survey data. Both Part C and D plans can use any CAHPS survey data collected for their internal quality improvement efforts.

In addition to modifying the 2020 data submission requirements for HEDIS and CAHPS surveys, CMS is taking the following action with respect to Part C and Part D 2021 Star Rating calculations:

• CMS will use last year’s HEDIS measures scores and ratings from the 2020 Star Ratings (based on care delivered in 2018) for the 2021 Star Ratings. Similarly, CMS
will use the CAHPS measures data scores and ratings (from the 2020 measure-level Star Ratings) for the 2021 Star Ratings.

- The measurement period and data for all other measures, where there was not a health and safety risk from the COVID-19 outbreak in collecting the data, will not change from what was finalized in the April 2018 final rule, unless:
  - In the event that the COVID-19 outbreak prevents CMS from having validated data or results in systemic data integrity issues for any other measures, we will replace the data about 2019 for which there are data quality issues due to the COVID-19 outbreak with the measure-level Star Rating and score from the 2020 Star Ratings;
  - In the event that CMS’s functions become focused on only continued performance of essential Agency functions and the Agency and/or its contractors do not have the ability to calculate the 2021 Star Ratings, the 2020 Star Ratings received for contract year 2020 would be used for the ratings for 2021.
  - For newer contracts where the 2021 Star Ratings would be the first year that they would receive a Star Rating, CMS will treat them as new for an additional year since CMS would not have enough data to assign a rating.

For the HEDIS and CAHPS measures that are part of the Part C and D improvement measures, CMS will use the measure-level improvement change score from the prior year and for all other measures will use the current measure-level improvement change score as has historically been done.

The Medicare program is also expanding participant appeals rights in Fee for Service, Medicare Advantage (MA), and Part D programs.3

**FDA Continues User-Fee Related Reviews Through COVID-19**

On April 16, 2020, the FDA released a statement4 concerning user fee review activities during COVID-19. The release states that the FDA continues to meet all their Medical Device User Fee Amendments (MDUFA) review goals. The statement indicates:

> We have taken steps to contact industry stakeholders to convert each previously scheduled meeting through May to a teleconference. For marketing applications on hold, we are further extending response due dates by 90 days for Premarket Notifications (510(k)s), Premarket Approval (PMA) applications (original and supplements), Humanitarian Device Exemption (HDE) applications (original and supplements) and De Novo classification requests. It is likely this extension of time will have an impact on the FDA and industry’s ability to meet the shared outcome goals for total time to decision as listed in the MDUFA IV commitment letter.

> Additionally, with many staff in CDRH working on COVID-19 activities related to pre-Emergency Use Authorizations (pre-EUAs), EUAs, and Immediately In Effect (IIE) guidance documents, it is possible that we will not be able to sustain our current level of performance indefinitely. However, this will be assessed on an ongoing basis.

> It is difficult to speculate on what the exact impact will be on incoming submissions moving forward. We are seeing and hearing from industry that companies are taking

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4 2020 WLNR 10946677
a role as partners in the defense of the public health by prioritizing their work and submissions.

As this remains an evolving and very dynamic situation, the FDA will continue to be flexible and as transparent as possible as we work to address the COVID-19 pandemic, as well as keep other key mission-critical initiatives unrelated to the pandemic moving forward.

**Trump Administration Announces Expanded Coverage for Essential Diagnostic Services Amid COVID-19 Public Health Emergency**

On April 11, the Centers for Medicare & Medicaid Services (CMS) and the Departments of Labor and the Treasury, issued guidance today to ensure Americans with private health insurance have coverage of 2019 Novel Coronavirus (COVID-19) diagnostic testing and certain other related services, including antibody testing, at no cost. As part of the effort to slow the spread of the virus, this guidance removes financial barriers for individuals to receive necessary COVID-19 tests and health services, as well as encourage the use of antibody testing that may help to enable health care workers and other Americans to get back to work more quickly.

In March, representatives of major health insurance companies met with President Trump, where they voluntarily committed to covering COVID-19 testing without cost sharing such as copays and coinsurance. Building on this commitment, today’s guidance implements the recently enacted Families First Coronavirus Response Act (FFCRA) and Coronavirus Aid, Relief, and Economic Security (CARES) Act, which require that private health issuers and employer group health plans cover COVID-19 testing and certain related items and services furnished during the COVID-19 pandemic, with no out-of-pocket expenses.

Specifically, the announcement implements the requirement for group health plans and group and individual health insurance to cover both diagnostic testing and certain related items and services provided during a medical visit with no cost sharing. This includes urgent care visits, emergency room visits, and in-person or telehealth visits to the doctor’s office that result in an order for or administration of a COVID-19 test. Covered COVID-19 tests include all FDA-authorized COVID-19 diagnostic tests, COVID-19 diagnostic tests that developers request authorization for on an emergency basis, and COVID-19 diagnostic tests developed in and authorized by states. It also ensures that COVID-19 antibody testing will also be covered. Once broadly available, a COVID-19 antibody test could become a key element in fighting the pandemic by providing a more accurate measure of how many people have been infected and potentially enabling individuals to get back to work more quickly.


**CMS Clarifies that Expenditures in the Community First Choice Program Qualify for the Increased FMAP set out in the Families First Act**

The Families First Coronavirus Response Act (P.L. 116-127), which President Trump (R) signed on March 18, 2020, includes a 6.2% increase in states’ federal medical assistance percentage (FMAP). The increase applies retroactively from January 1, 2020, and continues until the time that the public health emergency ends. However, states must meet certain requirements to claim the increase, and the increase does not apply to all expenditures. The government released an FAQ document to clarify the requirements for receiving the
increased FMAP. On April 13, 2020, CMS issued further guidance for both the Families First Act and the Coronavirus Aid, Relief and Economic Security (CARES) Act (P.L. 116-136), and it corrected an important misstatement in the first. In the in earlier guidance, CMS stated that the increased FMAP does not apply in certain situations where a special FMAP already applies, and it specifically listed the Community First Choice (CFC) program as one of them. In the more recent guidance, CMS clarified that the new FMAP does in deed apply to expenditures related to CFC:

We incorrectly stated that the 6.2 percentage point FMAP increase under the FFCRA [Families First Coronavirus Response Act] does not apply to Community First Choice (CFC) 1915(k) service expenditures, which are already eligible for a separate 6 percentage point FMAP increase. Expenditures for these services are, in fact, eligible for both the 6 percentage point FMAP increase under section 1915(k) of the Social Security Act and the 6.2 percentage point increase under section 6004 of the FFCRA, if the expenditures otherwise qualify. These FMAP increases are additive.

CARES Act Extends and Funds Important Health-Related Programs
The Families First Act and the Coronavirus Aid, Relief and Economic Security (CARES) Act (P.L. 116-136) includes a number of health-related provisions that affect the way health care is delivered. The provisions affecting health care delivery include these, among others:

- The act extends the Money Follows the Person program until November 30, 2020, and authorizes additional funds.
- The act extends the Medicaid Community Mental Health Services demonstration and directs the Health and Human Services (HHS) Secretary to select two more states to participate.
- It appropriates funds for fiscal years 2021 through 2025 for the Telehealth Network Grant Program and extends the grant period from four to five years.
- It temporarily allows federally-qualified health centers and rural health centers to render telehealth services to Medicare participants.
- The act allows hospice physicians or nurse practitioners to use telehealth for hospice face-to-face visits for the purpose of recertifying Medicare hospice eligibility.
- It directs the HHS Secretary to issue guidance about the use of telecommunications systems, including remote monitoring, for home health services.
- It adds to the list of providers who can order home health services in both Medicare and Medicaid.

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10 The Telehealth Network Grant Program, which is administered by the Health Resources and Services Administration, awards grants for demonstrations that use telehealth networks to improve access to care in underserved communities in rural, urban, and frontier settings. See "Telehealth Programs," HRSA, available at: [https://www.hrsa.gov/rural-health/telehealth](https://www.hrsa.gov/rural-health/telehealth).
The act clarifies that home- and community-based Medicaid services may be provided in an acute care hospital if they are identified in the patient’s service plan, meet needs that the hospital does not satisfy, do not substitute for services that the hospital is required to render, and are designed to ease the transition from acute care to home- and community-based services.11

**Trump Wants Masks on All Nursing Home Workers, Temperature Checks for All, and Separate COVID-19 Units**
The Trump Administration issued a set of "critical recommendations" for long-term care facilities.12 These recommendations state that every single person working in a nursing home wear a mask while working for the duration of the pandemic. It is also recommended that employees have their temperature checked prior to work and be checked for other symptoms.

These recommendations come alongside the finding that handwashing and infection control protocols continue to fall short of existing standards.

**Feds and States Under Pressure to Report COVID-19 Cases in Nursing Homes**
Federal health officials are coming under increasing pressure to start publicly tracking COVID-19 infections and deaths in nursing homes amid criticism of lack of transparency about outbreaks that have already claimed thousands of lives throughout the U.S. Experts say the lack of tracking and transparency has been a major blind spot, and that publicizing outbreaks as they happen could not only alert nearby communities and anguished relatives but also help officials see where to focus testing and other safety measures.13

Lacking federal reporting requirements, media sources have looked to media accounts and state health records to determine the scope of COVID-19 cases in long-term care facilities. *USA TODAY* reported on April 13 that at least 2,300 nursing homes have coronavirus cases but that new totals still represent an incomplete accounting due to the ongoing lack of widespread testing for the virus and inconsistent record-keeping from state to state. On the federal level, neither the CDC nor the Centers for Medicare and Medicaid Services is tracking the number of U.S. nursing homes with COVID-19 cases, or the number of total cases and fatalities in those facilities.14

At least 7,300 long-term care residents have died in 19 states as a result of COVID-19, a survey of state records by *ABC News* shows.15 The number nationwide is likely to be much

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higher as many states do not yet report such data and did not reply to requests for information.

In response to pressure to report COVID cases in nursing homes, CMS says that providers will soon be required to report potential infectious disease outbreaks directly to the Centers for Disease Control and Prevention. CMS Administrator Seema Verma said on April 15 that changes would be coming for nursing homes in response to the coronavirus pandemic. “[Nursing homes] do report this information to the local health departments, but we’re going to be enhancing our reporting requirements to get more real-time information about where there’s outbreaks across the country in nursing homes. So basically, enhancing their reporting directly to CDC,” Verma said during a call with members of the media.16 The new reporting requirements will help the agency focus its surveillance efforts, according to Verma. She also stressed the importance of having a strong surveillance system in place to help respond to future infections before they spread within a facility. Guidance on the new reporting requirements should be available for providers by the end of this week, Verma said, but did not specify what would be required, according to McKnight’s.

States have begun ratcheting up reporting requirements as well.

In Ohio, Dr. Amy Acton, the director of the Ohio Department of Health, signed a statewide order on April 15 that requires nursing homes, assisted-living centers and facilities for people with developmental disabilities to notify the families of residents within 24 hours when there are positive COVID-19 cases in one of those facilities.17

In Michigan, Governor Whitmer signed an executive order on April 15 requiring facilities to report confirmed cases of residents with COVID-19 to the state health department. Additionally, the executive order says employees must be informed of a COVID-19-affected resident “as soon as reasonably possible, but no later than 12 hours after identification.” Facilities must tell their local health department within 24 hours of identification about any resident with the coronavirus.18

In New York, the Department of Health released data on resident COVID-19 deaths in nursing homes (as of April 15).19 Governor Cuomo issued an updated executive order on April 16 requiring skilled nursing facilities, nursing homes, and adult care to notify family members or next of kin within 24 hours if any resident tests positive for COVID-19. The order also requires notification if any resident dies from the virus.

Nevada unveiled an online tool last week that allows people to track cases in specific nursing homes and other assisted living facilities.20

19 Available at: https://www.health.ny.gov/statistics/diseases/covid-19/fatalities_nursing_home_acf.pdf.
20 Facilities with Reported COVID-199 Cases, State of Nevada Department of Health and Human Services, available at: https://app.powerbigov.us/view?r=eyJrIjoiNDMwMjI0YmQtNmUyYS00ZmFjLWFiOWUtYzNhMi1jMjRkMjcwMzk4MCJ9.
CMS Allows Nurse Practitioners to Conduct Medical Exams at Nursing Homes During COVID-19 Pandemic

Nurse practitioners will be allowed to conduct certain medical exams on Medicare patients at nursing homes for the first time under a new policy announced on April 9 by the Centers for Medicare & Medicaid Services (CMS). “It’s all hands on deck during this crisis. All frontline medical professionals need to be able to work at the highest level they were trained for,” CMS Administrator Seema Verma said. In addition, doctors can now directly care for patients at rural hospitals, across state lines if necessary, via phone, radio, or online communication, without having to be physically present. The greater flexibility is part of a campaign to continue to meet patient needs, whether COVID-19 related or not, in the face of increased care demands. CMS’s workforce changes apply immediately and address supervision, licensure and certification, and other limitations in various healthcare settings. They are part of an array of temporary regulatory waivers and new rules issued recently by CMS and intended to help the American healthcare system respond to COVID-19.

CMS Waives Nurse Training Tasks During COVID-19 Pandemic

Hospice nurses will be relieved of hospice aide in-service training tasks so they can spend more time with patients under a new policy announced on April 9 by the Centers for Medicare & Medicaid Services (CMS). “It’s all hands on deck during this crisis. All frontline medical professionals need to be able to work at the highest level they were trained for,” CMS Administrator Seema Verma said. CMS’s workforce changes apply immediately and address supervision, licensure and certification, and other limitations in various healthcare settings. They are part of an array of temporary regulatory waivers and new rules issued recently by CMS and intended to help the American healthcare system respond to COVID-19.

OTHER REPORTS

MedPAC Recommends Pausing ACO Shared Savings

The Medicare Payment Advisory Commission (MedPAC) wrote a letter to Centers for Medicare & Medicaid Services (CMS) administrator Seema Verma recommending that the agency pause shared accountable care organization (ACO) savings and losses for the duration of the COVID-19 pandemic.

The Medicare Payment Advisory Commission is an independent congressional agency established by the Balanced Budget Act of 1997 (P.L. 105-33) to advise the U.S. Congress on issues affecting the Medicare program.

MedPAC acknowledged the competing priorities facing CMS during the pandemic and the steps the agency has taken to mitigate the financial impact of COVID-19 on ACO.

MedPAC then indicated, “ACOs should focus on their response to COVID-19 without concern for shared ACO savings or losses.”

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The agency noted that Medicare spending is uncertain in the face of the pandemic, which creates issues for providers participating in ACOs. Under the current system, 2020 performance will be judged based on benchmarks created prior to the pandemic.

MedPAC argued, “Given the dramatic shifts in care delivery that have occurred in 2020, attempting to adjust 2020 spending and benchmarks for COVID-19 will be impractical. It also may be inequitable. The degree to which different systems will have to divert resources to COVID-19 will vary widely depending on the provider's location and type of services provided.”

The agency recommended that CMS not look to 2020 data to evaluate the performance of ACOs.

MedPAC called on CMS to instead consider these actions:

- Do not use 2020 data to determine ACO performance for purposes of computing ACO quality, bonuses, or penalties. Consider extending all current ACO agreement periods by one year. In addition, do not use 2020 data in calculating baseline agreement year spending for future benchmarks.
- Do not use 2020 claims to assign beneficiaries to ACOs, since the shift to telehealth (possibly with physicians located very far away from beneficiaries) could distort ACO assignment. A determination could be made later about whether to use 2019 and/or 2021 claims to assign beneficiaries to ACOs in 2021.
- Allow a three-year extension of the NextGen ACO model through 2023. This will allow ACOs that have invested in the model to continue in the ACO program without having to adapt to a new model during this difficult time.
- Delay the start of the Center for Medicare and Medicaid Innovation Direct Contracting model by a minimum of one year to allow providers time to understand the new model (some features of which have not yet been established) prior to making commitments.

The agency indicated that similar modifications to other alternative payment models might be necessary, particularly for models with substantial two-sided risk.23

**NAACOS Opposes MedPAC Position on ACO Risk**

The National Association of ACOs (NAACOS) released a statement opposing MedPAC’s position on ACOs during COVID-19.

According to Clif Gaus, Sc.D., president and CEO of the National Association of ACOs, “The Medicare Payment Advisory Commission’s (MedPAC) recommendation to ignore shared savings in 2020 would devastate Medicare ACO programs.”

In 2018, ACOs saved $1.7 billion. Medicare paid approximately $900 million of those savings back to ACOs. In turn, ACOs directed that money toward quality improvement programs, care coordinators, health IT, analytics and additional infrastructure.

NAACOS indicated that ACOs need those funds to focus in improving the quality of patient care and addressing the treatment of chronic disease.

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The organization argued that the impact of the pandemic will vary regionally and in different health care markets throughout the United States.

Gaus stated, “To gut the savings opportunity before the data are in is presumptuous at best.”

He suggested a different approach of several policy options:
- Holding at-risk ACOs harmless, allowing ACOs the option to forego less in shared savings in order to take less risk;
- Allowing ACOs to change their risk track; and
- Extending the dropout deadline to give more time to understand how COVID-19 will play out in coming months.

Ten leading provider organizations have recommended holding downside risk ACOs harmless as a safety net for ACOs most affected by the pandemic in the coming months and potentially years.

According to Gaus, “MedPAC has consistently underplayed the value ACOs bring to Medicare payment reform. ACOs have saved Medicare billions of dollars and have done more to lower spending in a decade than all other reform efforts to date. Let’s hope CMS doesn’t accept this advice that would have detrimental effects on Medicare’s overall shift to value.”

**Deciding Who Gets Ventilators and Critical Care Resources During the COVID-19 Pandemic**

As the COVID-19 pandemic intensifies, providers are encountering shortages of critical care resources, such as ventilators and ICU beds, and the real possibility that they may have to decide which patients receive the life-saving care, and which do not. In *JAMA* Viewpoint, Douglas B. White, MD, MAS, and Bernard Lo, MD, consider the critical question: When demand for ventilators and other intensive treatments far outstrips the supply, what criteria should guide these rationing decisions?²⁵

**Categorically Excluding Large Groups of Patients From Receiving Mechanical Ventilation:** Although certain professional society guidelines and some state recommendations exclude from access to ICUs large groups of patients with certain comorbid conditions (such as heart failure, severe chronic lung disease, end-stage renal disease, and severe cognitive impairment), the authors find such exclusions not explicitly justified, and ethically flawed. The criteria for exclusion (long-term prognosis and functional status) are selectively applied to only some types of patients, rather than to all patients being considered for critical care. Moreover, categorical exclusions are too rigid to be used in a dynamic crisis, when ventilator shortages will likely surge and decline episodically during the pandemic, and such exclusions violate a fundamental ethical principle: use the means that are least restrictive to individual liberty to accomplish the public health goal.

**Focus on Survival to Hospital Discharge:** The commonly recommended approach to allocate ventilators to those patients most likely to survive to hospital discharge with treatment is inadequate because it ignores other relevant considerations, such as the number of years of life saved, or giving individuals equal opportunity to pass through the stages of life—


childhood, young adulthood, middle age, and old age. Persons who have essential responsibilities in saving lives during the pandemic, such as health care workers and first responders, also deserve heightened priority. Also, it should be made explicit that ventilators will not be allocated on the basis of morally irrelevant considerations, such as sex, race, religion, intellectual disability, insurance status, wealth, citizenship, social status, or social connections.

Recommendations for a Multiprinciple Allocation Framework: All patients who meet usual medical indications for ICU beds and ventilators are eligible and are assigned a priority score using a 1 to 8 scale based on (1) patients’ likelihood of surviving to hospital discharge, assessed with an objective measure of acute illness severity; and (2) patients’ likelihood of achieving longer-term survival based on the presence or absence of comorbid conditions. Also, individuals who perform tasks vital to the public health response are given heightened priority. In the event that there are ties in priority scores, life-cycle considerations are used as a tiebreaker, with priority going to younger patients, who have had less opportunity to live through life’s stages.

Withdrawing Life Support From One Patient to Provide It to Another: While the need to “reallocate” ventilators when capacity is overwhelmed is acknowledged, it will be distressing to health care workers, patients, and families, because in ordinary clinical care ventilators are withdrawn only if the family agrees. The following steps could improve such agonizing decisions:

- Ventilator use should be presented to patients and families as a time-limited therapeutic trial, not an unlimited promise.
- The duration of the trial of ventilation must not be too brief, to avoid a “rapid cycling” of withdrawing ventilators from patients who, if treated for several more days, would have survived.
- A triage officer or team, not the treating physician, should make decisions about allocating and discontinuing ventilators.
- When mechanical ventilation is discontinued, comprehensive palliative care is imperative. Family members of patients near death should be granted compassionate use of personal protective equipment if possible so that they can be with the dying patient. Health care workers will also need emotional support.

In conclusion, the authors urge hospitals and states to establish and implement policies that more fairly allocate scarce critical care resources and that better support dying patients and their families.

Nevada Extends Open Enrollment in Response to COVID-19
The health insurance exchange in Nevada announced that it would extend open enrollment to May 15 in response to the COVID-19 pandemic.

The Silver State Health Insurance Exchange decided to extend its limited-time Exceptional Circumstance Special Enrollment Period (SEP) for qualified residents of Nevada to purchase health insurance coverage through the marketplace.

Governor Sisolak declared an emergency in Nevada on March 12. In response, the state-run health insurance exchange decided to extend open enrollment to April 15. The special enrollment period will now extend an additional month.

Consumers enrolling in a plan through the exchange before April 30 will receive coverage beginning May 1, 2020.
Consumers enrolling between May 1-15 will have coverage beginning June 1, 2020.

“COVID-19 does not discriminate. Anyone, regardless of age, income or health can become infected,” said Gov. Steve Sisolak. “If you or your family don’t have health insurance, now is the time to get it. Don’t wait for a health crisis, particularly this one, to affect you personally. Take advantage of this opportunity to enroll in a plan for which you may even qualify for subsidies. There is no time like the present.”

All health insurance plans available through Nevada Health Link cover the ten essential health benefits mandated by the Affordable Care Act. Coverage includes emergency care and hospitalization.

Care related to COVID-19 is covered by all plans offered through the Nevada exchange.

By purchasing health insurance plans through Nevada Health Link, eligible consumers can access federal subsidies to help cover the cost of insurance premiums. Over 80 percent of Nevada consumers who access plans through the exchange are eligible for some amount of federal subsidy.

“Unprecedented times call for unprecedented measures like Nevada Health Link’s exceptional circumstance special enrollment period, and everyone who is uninsured or didn’t obtain coverage during the normal open enrollment period should jump now at the opportunity to get health insurance,” said Dr. Florence Jameson, chair of the board for Silver State Health Insurance Exchange. “As a longtime practicing Nevada physician, I have treated patients from all walks of life and know first-hand the value of insurance, which becomes glaringly more evident during a pandemic like the novel Coronavirus. With the uncertainty that comes with this virus, we encourage all uninsured Nevadans to explore one of the plans offered on Nevada Health Link to not only prevent possible financial burden, but more importantly to ensure a higher quality of care if it is needed.”

According to Executive Director for Silver State Health Insurance Exchange, Heather Korublic, “Gov. Sisolak has encouraged everyone to continue to ‘Stay Home for Nevada,’ so we are extending our Special Enrollment Period to allow uninsured and underinsured Nevadans extra time to purchase comprehensive insurance plans on Nevada Health Link. As experts anticipate the number of positive COVID-19 cases in our state to soon reach its peak, we want to remind Nevadans of the critical importance of protecting themselves and their families from financial ruin if a medical issue or accident occurs, especially during these uncertain times. Peace of mind to have your health needs taken care of is invaluable, and Nevada Health Link is here and ready to help you secure a healthcare plan for you and your family.”

**Vermont Requires Coverage of COVID-19 Diagnosis and Treatment**

Vermont governor Phil Scott and the Department of Financial Regulation (DFR) announced an emergency regulation requiring commercial health insurers to cover the cost of the diagnosis and treatment of COVID-19 without cost-sharing to beneficiaries.

Insurers will not be able to charge consumers co-payments, coinsurance or deductibles for the cost of treatment or diagnosis of the virus.

Governor Scott declared a State of Emergency on March 13, 2020. The emergency regulation will apply retroactively to that date.
"During this unprecedented emergency, Vermonters deserve access to the care they need to stay safe and healthy," said Governor Scott. “As we work to expand testing to more Vermonters with symptoms of COVID-19, it is critical that our efforts to help control the spread of the virus are not affected by insurance costs.”

The regulation will apply to fully funded health insurance plans, including plans sold through the health insurance exchange and plans sold to large group employers.

DFR rules require insurers to cover out-of-network services for beneficiaries if in-network providers are not available.

“The COVID-19 pandemic has evolved quickly and is impacting the economic lives of so many Vermonters,” said DFR Commissioner Michael Pieciak “Accordingly, we have been working closely with our health insurers to eliminate financial barriers to testing and treatment of the disease.”

DFR previously undertook a series of actions addressing the COVID-19 outbreak:
• March 6, 2020: DFR issued an emergency bulletin requiring insurers to cover the cost of COVID-19 testing.
• March 20, 2020: DFR issued guidance to insurers to provide additional grace periods to Vermonters who are struggling to pay their health insurance premiums.
• March 30, 2020: DFR issued an emergency regulation to expand the coverage of telehealth and audio-only medical visits.26

Insulin Manufacturers Offer Lower Cost Options to Patients During COVID-19 Pandemic
Eli Lilly and Sanofi, two of the largest manufacturers of insulin products, are responding to the COVID-19 pandemic with programs intended to provide patients with continued access to insulin products.27

Sanofi has created two platforms for insulin patients. One is for patients with insurance and one is for those without. Those with insurance are eligible for the company’s co-pay assistance programs, where most participants will pay $10 or less per month for their products, regardless of their income level. This program includes Adlyxin (lixisenatide) injection, Apidra (insulin glulisine injection) 100 Units/mL, Lantus (insulin glargine injection) 100 Units/mL, Toujeo (insulin glargine injection) 300 Units/mL, Soliqua 100/33 (insulin glargine, and lixisenatide injection) 100 Units/mL and 33 mcg/mL.

For those with no health insurance, Sanofi created the Insulins Valyou Savings Program, where all uninsured patients (regardless of income level) can purchase one or multiple Sanofi insulins (Lantus, Toujeo, Admelog, and Apidra) for a fixed price of $99 per month.

A statement from Sanofi noted that, “The intent of this program is to provide relief for those currently paying the highest prices for their insulin due to lack of insurance coverage and do not qualify for other assistance programs.”

Eli Lilly has also introduced the Lilly Insulin Value Program. This program allows anyone with or without insurance to fill their monthly prescription of Lilly insulin at a capped price of $35. The program covers most Lilly insulins including all Humalog (insulin lispro injection 100 units/mL) formulations.

Diabetes patients who use Lilly products are encouraged to call the Lilly Diabetes Solution Center at (833) 808-1234.

**Georgia Resident Arrested for Selling Illegal Products Claiming to Protect Against Viruses**

A Georgia resident made her initial appearance on federal charges of illegally importing and selling an unregistered pesticide, Toamit Virus Shut Out, through eBay, claiming that it would help protect individuals from viruses, according to the Department of Justice (DOJ) on April 9.

Rong Sun, aka Vicky Sun, 34, of Fayetteville, Georgia, was charged with a criminal complaint filed by the U.S. Attorney’s Office on April 8, 2020, and made her initial appearance today before U.S. Magistrate Judge Alan J. Baverman.

“The defendant took advantage of the current worldwide crisis to sell an illegal product with the claim that it protects individuals from viruses,” said U.S. Attorney Byung J. “BJay” Pak of the Northern District of Georgia. “We will take quick action through the Georgia COVID-19 Task Force to put a stop to criminals preying on the public with Coronavirus-related fraud schemes.”

“Reliance on fraudulent products may increase the spread of COVID-19 and exacerbate the current public health emergency,” said Environmental Protection Agency (EPA) Assistant Administrator for Enforcement and Compliance Assurance Susan Bodine. “EPA and our law enforcement partners are working hard to keep these illegal products off the shelves, off the internet, and out of this country. We ask American consumers to help by checking the list of approved products found at epa.gov/coronavirus before making any purchases.”

“The sale of this product not only violates several federal laws, it also gives people a false hope. During a global crisis, like we are experiencing right now, it is incredibly dangerous and reckless to exploit people’s fear for profit,” said U.S. Immigration and Customs Enforcement’s Homeland Security Investigations (HSI) acting Special Agent in Charge Robert Hammer, who oversees operations in Georgia and Alabama. “HSI Atlanta, in conjunction with our law enforcement partners, will continue to prioritize our efforts to protect Americans from COVID-19 fraud.”

According to the charges, the defendant sold an unregistered pesticide, Toamit Virus Shut Out, through eBay, claiming that it would help protect individuals from viruses. The pesticide was marketed as “Virus Shut Out” and “Stop The Virus.”

Additionally, the listing stated that “its main ingredient is ClO2, which is a new generation of widely effective and powerful fungicide recognized internationally at present. Bacteria and viruses can be lifted up within one meter of the wearer’s body, just like a portable air cleaner with its own protective cover.” It also stated that “In extraordinary times, access to public places and confined spaces will be protected by one more layer and have one more layer of safety protection effect, thus reducing the risks and probability of infection and transmission.”
The listing further claimed that Toamit is “office and home essential during viral infections reduce transmission risk by 90%.”

An indictment is merely an allegation and the defendant is presumed innocent until proven guilty beyond a reasonable doubt in a court of law.

REGULATORY INTELLIGENCE AND REUTERS NEWS

U.S. DEA Relaxes Production Limits on Controlled Drugs for COVID-19 Patients
(Reuters) - The U.S. Drug Enforcement Administration said on Tuesday it was increasing production limits by 15% for certain controlled substance medicines that were in high demand due to the COVID-19 pandemic.28

The agency’s directive includes painkillers, such as fentanyl, morphine and hydromorphone, and certain cough or cold-medicine ingredients like codeine, ephedrine and pseudoephedrine.

U.S. doctors running out of narcotics needed for COVID-19 patients had asked the federal government to raise production limits for drugmakers, after national quotas had been tightened to address the opioid addiction crisis. (https://reut.rs/2Xk7P94)

The DEA had previously reduced the overall fentanyl quota by over 30% for 2020.

The agency said on Tuesday it would also increase the production allowance for opioid-addiction drug methadone to ensure that opioid treatment programs have sufficient supplies to treat patients suffering from opioid use disorder.

"Although the existing 2020 quota level is sufficient to meet current needs, DEA is acting proactively to ensure that — should the public health emergency become more acute — there is sufficient quota for these important drugs," it said.

The DEA said it would also approve increases in imports of medications necessary for patients on ventilators, including painkiller ketamine, sedatives such as diazepam, midazolam, and lorazepam, and epilepsy drug phenobarbital.

The agency said it would reevaluate demand after the coronavirus outbreak abates and would adjust production quotas as needed.

The DEA last month agreed to relax inventory controls for manufacturers, allowing them to produce and store more than 65% of their annual quota throughout the duration of the emergency.

CMS Doubles Medicare Payment to $100 for Some COVID-19 Lab Tests
CMS on April 15 said it would nearly double Medicare reimbursements for certain COVID-19 lab tests in an effort to bolster testing in the United States. The program would reimburse $100 for tests that use technologies developed by private companies, which provide faster results and can process more than two hundred samples a day. "This is an absolute game-changer for nursing homes, where risk of Coronavirus infection is high among our most

vulnerable," CMS Administrator Seema Verma said in a statement. Nursing homes have been particularly vulnerable to the virus that spreads by respiratory droplets, causing severe symptoms in people with weak immune systems and underlying health conditions. The reimbursement rate for other coronavirus lab tests will be decided by local Medicare administrative contractors that are currently paying about $51 for those tests, the agency said.29