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://gori.tr.com/fuaD4N.

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STATE ACTIONS

Massachusetts
• The Center for Health Information and Analysis (CHIA) is issuing this Administrative Bulletin pursuant to 957 CMR 9.11 to notify Hospitals required to submit data to CHIA in accordance with 957 CMR 9.07 of changes to the Quarterly and Annual Standardized Financial Filing requirements for Acute Hospitals, Physician Organizations, and their Parent Organization. See 2020 MA REG TEXT 564586 (NS).
• Chapter 101 CMR 445.00 establishes the payment rates for certain day programs in response to the coronavirus disease 2019 (COVID-19) emergency. These services are purchased by the Department of Developmental Services (DDS), the Massachusetts Commission for the Blind (MCB), the Massachusetts Rehabilitation Commission (MRC), and MassHealth. See 2020 MA REG TEXT 564587 (NS).

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

2019 MI S.B. 1094 (NS), introduced September 9, nursing homes; admittance of COVID-19-positive patients to nursing homes from another facility; prohibit, and develop centralized intake facilities.

**New York**

- 2019 NY A.B. 10966 (NS), introduced September 9, relates to providing for nursing home residents to designate an essential person who would be permitted to be present and provide aid at a nursing home.
- 2019 NY A.B. 11000 (NS), introduced September 9, requires the office for people with developmental disabilities, department of health and division of the budget to authorize voluntary providers of supports and services to individuals with intellectual and developmental disabilities to bill and be reimbursed within thirty days of billing for novel coronavirus, COVID-19 related costs and expenses, including, but not limited to, increased staffing and personal costs, personal protective equipment expenses, and increased residential cost.

**Oregon**

- This rule will facilitate clients' access to urgently needed telephone and telemedicine services. It will mitigate the risk of financial harm to key providers and reduce barriers to provision of key services with less risk of contagion of COVID-19. This rulemaking action will avoid or mitigate the risks mentioned above by incorporating in rule the technical changes and interim modifications as specified in the Prioritized List of Health Services. See 2020 OR REG TEXT 560149 (NS).
- This rule is necessary in order to support appropriate response to the COVID-19 pandemic and assure appropriate, safe, timely access to qualified health care providers for Oregon Health Plan members. See 2020 OR REG TEXT 560150 (NS).

**REGULATORY INTELLIGENCE AND REUTERS NEWS**

**U.S., European COVID-19 Vaccine Developers Pledge to Uphold Testing Rigor**

(Reuters) - Nine leading U.S. and European vaccine developers pledged on Tuesday to uphold the scientific standards their experimental immunizations will be held against in the global race to contain the coronavirus pandemic.²

The companies, including Pfizer, GlaxoSmithKline and AstraZeneca, issued what they called a “historic pledge” after a rise in concern that safety and efficacy standards might slip in the rush to find a vaccine.

The companies said in a statement they would “uphold the integrity of the scientific process as they work towards potential global regulatory filings and approvals of the first COVID-19 vaccines.”

The other signatories were Johnson & Johnson, Merck & Co, Moderna, Novavax, Sanofi and BioNTech.

The promise to play by established rules underlines a highly politicized debate over what action is needed to rein in COVID-19 quickly and to jumpstart global business and trade.

Partners BioNTech and Pfizer could unveil pivotal trial data as early as October, potentially placing them at the center of caustic U.S. politics before the Nov. 3 presidential election.

“It is playing out to be a very bitter and emotionally-charged election,” said Joseph Kim, chief executive officer at San Diego-based vaccine developer Inovio Pharmaceuticals Inc (INO.O), which was not asked to sign the document. “The pledge, without being political, is saying we are going to put the safety and health of the public forward as the No. 1 priority.”

The head of the U.S. Food and Drug Administration (FDA) said last month COVID-19 vaccines may not necessarily need to complete Phase 3 clinical trials - large-scale testing intended to demonstrate safety and efficacy - as long as officials are convinced the benefits outweigh the risks.

This prompted a call for caution from the World Health Organization (WHO).

Developers globally have yet to produce large-scale trial data showing actual infections in participants, yet Russia granted approval to a COVID-19 vaccine last month, prompting some Western experts to criticize a lack of testing.

The head of China’s Sinovac Biotech has said most of its employees and their families have already taken an experimental vaccine developed by the Chinese firm under the country’s emergency-use program.

Chinese companies or institutions, which are involved in several leading vaccine projects, did not sign the statement.

PROMISE ON SAFETY AND EFFICACY

“We want it to be known that also in the current situation we are not willing to compromise safety and efficacy,” said co-signatory Ugur Sahin, chief executive BioNTech.

“Apart from the pressure and the hope for a vaccine to be available as fast as possible, there is also a lot of uncertainty among people that some development steps may be omitted here.”

President Donald Trump has said it is possible the United States will have a vaccine before the November election.

The nine companies said they would follow established guidance from expert regulatory authorities such as the FDA.

Among other hurdles, approval must be based on large, diverse clinical trials with comparative groups that do not receive the vaccine in question. Participants and those working on the trial must not know which group they belong to, according to the pledge.

BioNTech’s Sahin said there must be statistical certainty of 95%, in some cases higher, and that a positive reading on efficacy does not come just from random variations but reflects the underlying workings of the compound.

The development race has intensified safety concerns about an inoculation, polls have shown.
Western regulators have said they would not cut corners but rather prioritize the review workload and allow for development steps in parallel that would normally be handled consecutively.

Sahin declined to comment on regulators specifically or on what events prompted the joint statement.

The chief executive of German vaccine developer Leukocare, which did not sign the pledge, was more forthright.

“What Russia did - and maybe also there are tendencies in the U.S. to push the approval of a vaccine which has not been sufficiently developed in clinic – bears a huge risk,” said CEO Michael Scholl.

“My biggest fear is that we will approve vaccines that are not safe and that will have a negative impact on the concept of vaccinations in general.”