SQUIRE PATTON BOGGS

COVID-19 and US Health Insurance

New Regulatory Directives

MARCH 13, 2020

Coronavirus disease 2019 (COVID-19) is a rapidly spreading global health problem. Over the past week, state and federal regulators have issued guidance and imposed requirements on health insurance companies and managed care plans (health insurers) to broaden and tailor coverage to COVID-19. This alert serves as a guide to assist our clients with understanding the new Ohio and federal regulatory requirements and expectations. Guidance regarding state distinctions will follow in a supplement to this alert.

Federal Guidance

A. Medicare Advantage Plans

The Centers for Medicare & Medicaid Services (CMS) issued guidance to Medicare Advantage Organizations (MA Plans) as to their obligations and permissible flexibilities related to the emergency caused by COVID-19.

i. Medicare Advantage Special Requirements

Under federal law, if a governor declares a state emergency under 42 CFR 422.100(m), Medicare beneficiaries in that state can gain access to additional Medicare benefits for 30 days or the date identified in the governor's declaration. To date, 29 states and the District of Columbia have issued emergency declarations to broaden Medicare benefits.[1]

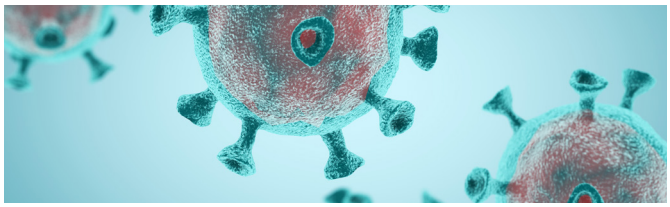
After a state declares an emergency, the requirements for MA Plans under 42 CFR 422.100(m)(1) are as follows:

- Cover Parts A and B services and Part C benefits at non-contracted facilities, if the facilities participate in Medicare
- Waive, in full, requirements for gatekeeper referrals, where applicable
- Provide the same cost sharing for the enrollee as if the service or benefit had been provided at a plan-contracted facility
- Make changes that benefit the enrollee effective immediately without the 30-day notification requirement as required by § 422.111(d)(3)

ii. MA Plan Permissive Actions

In response to the unique circumstances resulting from the outbreak of COVID-19, CMS advises that MA Plans may:

- Waive or reduce enrollee cost sharing for COVID-19 lab tests, telehealth benefits and other services to address the outbreak, provided that MA Plans waive or reduce cost sharing for all similarly situated enrollees on a uniform basis with CMS approval
- Provide enrollees with access to Medicare Part B services via telehealth in any geographic area and various locations, including at enrollees' homes, provided this benefit is provided to all similarly situated enrollees impacted by the outbreak
- Waive plan prior authorization requirements that otherwise would apply to tests or services related to COVID-19



If these changes are implemented with CMS approval, these changes to benefit enrollees will fall under the safe harbor to federal anti-kickback statute set forth in 42 CFR 1001.952(l).

iii. Medicare Part D Sponsors

PDPs may also take the following actions to ensure pharmacy benefits are accessible while the COVID-19 outbreak remains an emergency:

- **Relax "refill-too-soon" edits and provide maximum extended supply** – PDPs may relax their "refill-too-soon" edits if the PDP reasonably expects a disruption in access to drugs. Whenever PDPs make the decision to turn edits back on, they should work closely with all enrollees, particularly those who indicate that they are still displaced or otherwise impacted by the disaster or emergency.
- **Reimburse enrollees for prescriptions obtained from out-of-network pharmacies** – PDPs must ensure enrollees have adequate access to covered Part D drugs dispensed at out-of-network pharmacies when those enrollees cannot reasonably be expected to obtain covered Part D drugs at a network pharmacy. Enrollees remain responsible for cost sharing associated with such drugs.
- **Home or mail delivery of Part D drugs** – PDPs may voluntarily relax plan-imposed policies that discourage certain methods of delivery, such as mail or home delivery.
- **Prior authorization for Part D drugs** – PDPs may waive prior authorization requirements that otherwise would apply to Part D drugs used to treat or prevent COVID-19. Any such waiver must be uniformly provided to similarly situated enrollees who are affected by COVID-19.
- **Drug shortages** – PDPs should follow the existing drug shortage guidance in response to any shortages that result from this emergency.
- **Vaccines** – When vaccines become available for COVID-19, Medicare will cover the vaccine. All Part D plans will be required to cover the vaccine if it is a Part D drug.

1 Note this number continues to develop. *See* https://www.nga.org/coronavirus/

B. Medicaid and CHIP

Medicaid, including Children's Health Insurance Program (CHIP), guidance has been left to the states. Health insurers, state officials and interested parties are urging state Medicaid programs to cover COVID-19 testing and treatment without cost sharing, which the Trump Administration has pressed commercial insurers to do. As of now, CMS has only issued a COVID-19 factsheet, which outlines current Medicaid and CHIP coverage. Accordingly, whether COVID-19 testing is categorically covered without patient cost sharing is being determined on a state-by-state basis, and is continuing to develop.

Medicaid currently offers a range of benefits that would include the testing and treatment of COVID-19, including testing, diagnostics and lab services, immunizations, inpatient and outpatient hospital services, prescription drugs, nursing and rehabilitation facilities, emergency services, child health services and telehealth. Experts are encouraging state Medicaid programs to tailor their benefit plans to COVID-19, and changes are expected to occur on a state-by-state basis.

Private Market

Existing federal rules adopted by CMS under the Affordable Care Act (ACA) governing individual and small group coverage of Essential Health Benefits (EHB) apply to the diagnosis and treatment of COVID-19. How these benefits are interpreted may vary by state and plan. Large group and self-insured plans are not subject to the federal EHB rules, but are subject to state regulation or, in the case of self-funded plans, other federal regulation that is not triggered by the emergency declarations issued to date. For large group plans, health insurers have made voluntary commitments regarding diagnostic and laboratory services, as described below.

COVID-19 treatment impacts the following individual and small group market coverage requirements (and large group, where indicated):

- **Diagnostics and laboratory services**:
  - **Individual and small group plans** – Lab services are EHBs that must be covered, subject to state benchmark plans definitions. Health insurers retain the ability to assess whether any specific test is medically necessary and effective, and prior authorization may still apply to certain tests and procedures.
  - **Large group and self-insured plans** – Many health insurers have voluntarily agreed to waive copays for safe and effective COVID-19 testing per negotiations with the Trump Administration. Mandates to waive consumer cost sharing are being issued by state insurance regulators.
- **Vaccines** – When a vaccine is developed for COVID-19, it is expected to be a preventive service that all individual and group plans must cover as an EHB without cost sharing.
- **Hospitalization and ambulatory patient services** – Hospitalization, ambulatory and emergency services are EHBs that individual and small group plans must cover. Standard cost sharing applies for these services.
- **Telehealth** – Telehealth services are not required by federal law, but are already covered by many health insurance companies. Standard cost sharing may apply.
- **Prescription drugs** – Prescription drugs are EHBs that individual and small group plans must cover. While there are minimum requirements for drugs to be included on formularies, not all drugs may be covered. Notwithstanding, health insurers generally have exception processes where formulary drugs are not effective at treating a condition, and non-formulary drugs are medically necessary. The federal government has not taken action to require that any specific drug be added to plan formularies, but some plans are taking action voluntarily.
- **Health savings accounts (HSAs) and high-deductible health plans (HDHPs)** – Group health plans commonly offer employees the option to enroll in HDHPs tied to HSAs. The IRS issued guidance this week that, with respect to HDHPs, group health plans and insurance companies may pay for the treatment and testing for COVID-19 without requiring the enrollee to first satisfy the deductible. IRS Notice 2020-15. Group health plans and insurance companies can now pay for these services with first dollar coverage and still maintain the tax-favored treatment of HSA plans.

State Guidance

Ohio

The Ohio Department of Insurance (ODI) issued Bulletin 2020-02 (Access to Coverage for Ohioans Impacted by the COVID-19 Virus) on March 11, 2020, notifying companies of their obligations to ensure access to the healthcare services to test and treat COVID-19.

For health insurance, ODI reminded health insurers of certain coverage obligations, such as the following:

- To apply a prudent layperson standard to emergency services related to COVID-19 and related symptoms
- To evaluate the appropriateness of utilization management techniques as applied to the testing or treatment of COVID-19
- To encourage health insurers to cover telemedicine, and where telemedicine is covered, to cover telemedicine services related to COVID-19 testing and treatment
- To afford insureds the opportunity to appeal claims denials and to request external review
- To ensure that provider networks are adequate to handle testing and care for COVID-19
- To provide both standard and expedited formulary exceptions for non-formulary drugs; and to authorize extended supplies as medically appropriate
- To keep consumers informed about available benefits, to ensure that nurse helplines are appropriately staffed, to respond timely to inquiries, and to make necessary and useful information available on their websites

As to travel insurance, ODI Bulletin 2020-02 states that unless a specific exclusion encapsulating COVID-19 applies, a travel insurance policy that covers sickness, accident, disability or death must cover all risks related to COVID-19 according to the terms of the policy.

Importantly, ODI instructed insurers that any insurer unable or unwilling to comply with the recommendations made in the bulletin above must inform the ODI of the reasons for its inability or unwillingness to comply within five working days from the effective date of this Bulletin, so by March 18, 2020.

Other States Responses

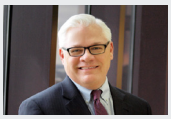
In the past several days, more than 29 states have issued guidance to insurance companies offering coverage within their jurisdictions. A supplement to this alert will follow outlining those updates. We will also continue to monitor guidance and direction issued from the federal government in this rapidly changing regulatory environment.

Conclusion

For questions or assistance in the implementation of the above guidelines, please contact Doug Anderson, Mary Jo Hudson or Meghna Rao.

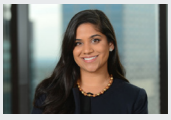
For additional information, our Coronavirus Resource Hub provides guidance on key legal issues for businesses to consider, together with some practical steps for businesses to take.

Contacts



Douglas Anderson
Principal, Columbus
T +1 614 365 2717
E doug.anderson@squirepb.com

Mary Jo Hudson
Partner, Columbus
T +1 614 365 2732
E mj.hudson@squirepb.com



Meghna Rao
Associate, Columbus
T +1 614 365 2880
E meghna.rao@squirepb.com