

[Address here]

[To be addressed to State Governors, Insurance Commissioners, Medicaid Directors, and Executive Directors Boards of Pharmacy]

Dear _____:

On behalf of **the undersigned patient organizations** representing the estimated 30 million Americans living with rare diseases, we write to commend your ongoing efforts to protect the public's health and urge you to protect rare disease patients and high-risk populations during the COVID-19 crisis by:

- Issuing an emergency regulation requiring that insurers operating within the state of **[STATE NAME]** allow a one-time 90 day refill of covered prescription medications and lift barriers to obtaining medication from out-of-network pharmacies;
- Preparing for the possibility of supply chain disruptions by requiring insurers to cover off-formulary prescription drugs if there is not a formulary drug available to treat the insured;
- Ensuring prior authorization and reauthorization requirements do not impede access to care and treatment;
- Facilitating authorization of home infusion and home injection services and ensure reimbursement rates appropriately reimburse for such services;
- Requesting authority to extend appeal and fair hearing deadlines to ensure important protections for patients who are seeking access to care and treatment; and
- Seeking flexibilities afforded under section 1135(b)(1)(C) of the Social Security Act

The CDC is currently advising people at high risk of complications – a group including people with rare diseases, disabilities, seniors, and those with chronic illnesses – to obtain and keep on hand a supply of prescription medications in the event that staying at home for prolonged periods of time becomes necessary.¹ In practice, this is not feasible for most, since payers rarely cover refills until 3 to 7 days before a prescription is expected to run out.

Options for Addressing Barriers to Prior Authorizations, Reauthorizations, and Appeal Deadlines

¹ Centers for Disease Control and Prevention. (2020, March 8). People at risk for serious illness from COVID-19. Retrieved from: <https://www.cdc.gov/coronavirus/2019-ncov/specific-groups/high-risk-complications.html>.

In the coming weeks, providers and patients may be unable to complete assessments required for prior authorization within the timeframe required for authorization for a variety of reasons which may include a patient's inability to travel to clinic appointments, or cancellation of clinic appointments due to diversion of health care resources or as part of facility closures and restrictions on peer to peer contact in the clinical setting.

In an effort to ensure continuity of care and treatment CMS on March 17 granted flexibility to Florida Medicaid through an 1135 waiver to ease prior authorization and medical necessity processes.²

Furthermore, we urge states to request authority to extend appeal and fair hearing deadlines to ensure important protections for patients who are seeking access to care and treatment. Such flexibilities were granted by CMS to the state of Florida.

Home Infusion and Home Injection Services

Home infusion and home injection therapies provide effective additional site-of-service for some of Medicaid and Medicare's most vulnerable patients – such as those with rare diseases who may be at greater risk of critical illness or death from COVID-19. Home infusion and home injection offer important alternatives to the hospital outpatient department setting of care for at risk individuals, and for those individuals who do not have access to this health care setting due to facility closure and or diversion of health care and transportation resources during this public health crisis.

To that end, we urge states to take immediate action to allow for the transition of physician-administered therapies to the home setting as appropriate. Furthermore, we encourage states to ensure a reimbursement mechanism that fully reimburses providers for home infusion and home injection services.

Measures to Prevent Medication Disruption

Medication disruption endangers people's lives, both in and of itself and because the resulting destabilization of chronic conditions may worsen outcomes of acute illnesses like COVID-19. If this issue is not addressed, many of our state's residents at greatest risk of critical illness or death from COVID-19 will be forced to choose between traveling to pharmacies despite an active outbreak or abruptly discontinuing maintenance medication. In the event that drug shortages or shipment disruptions occur during an outbreak, some patients may be unable to obtain medication at all. It also increases the risk of acute health crises requiring hospitalization at a time when healthcare systems are already at serious risk of exceeding capacity.

²Centers for Medicare & Medicaid Services. Section 1135 Flexibilities Requested in March 13, 2020 Communication. (2020, March 17). <https://www.medicaid.gov/state-resource-center/downloads/fl-section-1135-appvl.pdf>

Recognizing the urgency of the situation, on March 5th the Washington State insurance commissioner issued an emergency order requiring insurers to cover a one-time early refill of prescription medications.³ On March 10th, the Centers for Medicare and Medicaid Services issued guidance to Medicare Part D plans reminding them of their ability to relax restrictions on early refills and lift barriers to obtaining prescriptions from out-of-network pharmacies.⁴ New York State recently directed insurers to provide insurance coverage for off-formulary prescription drugs if there is not a formulary drug available to treat the insured.⁵ All of these are measures we urge you to incorporate into your state response to COVID-19.

Some insurers have already chosen to allow early refills on their own initiative.⁶ We urge you to act to ensure *all* of our state's residents covered by public or private insurance can obtain a sufficient supply of prescription medication, including specialty drugs, to protect their health during this crisis.

Section 1135 Waivers

The national emergency declaration enables CMS to grant state and territorial Medicaid agencies a wider range of flexibilities under section 1135 waivers.⁷ We urge every state to seek the fullest extent of flexibilities possible in order to ameliorate the burden on patients with rare disease and the providers who serve them.

We urge all states to seek flexibilities afforded under section 1135(b)(1)(C) of the Social Security Act to waive prior authorization requirements for care and treatments through the termination of the emergency declaration and for at least 90 days thereafter to allow patients and clinics appropriate time to complete assessments as needed. Importantly, notwithstanding the emergency declaration, federal statute requires state Medicaid programs provide access to treatments prescribed in accordance with the FDA-approved indication without delay.⁸

As has been demonstrated elsewhere, once active community transmission begins, the crisis develops rapidly. We ask you to treat this as a public health emergency. To protect vulnerable

³ State of Washington, Office of Insurance Commissioner. (2020, March 5). Emergency Order No. 20-01. Retrieved from <https://www.insurance.wa.gov/sites/default/files/documents/emergency-order-number-20-01.pdf>.

⁴ Centers for Medicare & Medicaid Services. (2020, March 10). Information Related to Coronavirus Disease 2019 - COVID-19. Retrieved from <https://www.cms.gov/files/document/hpms-memo-covid-information-plans.pdf>.

⁵ Office of Governor Andrew M. Cuomo. (2020, March 2). Governor Cuomo announces new directive requiring New York insurers waive cost-sharing for coronavirus testing. Retrieved from <https://www.governor.ny.gov/news/governor-cuomo-announces-new-directive-requiring-new-york-insurers-waive-cost-sharing>.

⁶ Neighmond, P. (2020, March 9). How to boost your emergency supply of prescription medicines. *National Public Radio*. Retrieved from <https://www.npr.org/sections/health-shots/2020/03/09/813704598/how-to-boost-your-emergency-supply-of-prescription-medicines>.

⁷ Centers for Medicare & Medicaid Services. 1135 Waivers. (2017, December 12). <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertEmergPrep/1135-Waivers>

⁸ Social Security Act § 1927(k)(6)

residents of **[STATE NAME]**, we urge you to act with the utmost urgency to require insurers to cover early refills and remove barriers to filling them.

We thank you for your prompt attention to this matter. Please do not hesitate to contact Steve Silvestri, Director of Public Policy (ssilvestri@everylifefoundation.org) or Annie Kennedy, Chief of Policy and Advocacy (akennedy@everylifefoundation.org) at the EveryLife Foundation for Rare Diseases with any questions.

Sincerely,