

March 25, 2020

[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 to patients with complex medical conditions when deemed appropriate by a physician 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.

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>.

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

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

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>

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.

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, complex medical conditions, and high risk populations, 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

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)

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 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,

ADAP Advocacy Association
ADCY5.org
Advocacy & Awareness for Immune Disorders Association (AAIDA)
Aimed Alliance
Alabama Rare
Alagille Syndrome Alliance
AliveAndKickn
Alliance for Patient Access
Alliance to Solve PANS & Immune-Related Encephalopathies
ALS Association
American Autoimmune Related Disease Association (AARDA)
American Behcet's Disease Association
American Bone Health
American Cancer Society Cancer Action Network
American Kidney Fund
American Liver Foundation
American Partnership for Eosinophilic Disorders
American Porphyria Foundation
Answer Cancer Foundation (AnCan)
APS Foundation of America, Inc
Association for Frontotemporal Degeneration
Avery's Angels Gastroschisis Foundation
Avery's Hope
Bridge the Gap – SYNGAP Education and Research Foundation
California Chronic Care Coalition
CancerCare
Caregiver Action Network
CDG CARE
Child Neurology Foundation
Children's Tumor Foundation
Chronic Care Policy Alliance
Chronic Disease Coalition

Citizens United for Research in Epilepsy (CURE)
Community Access National Network (CANN)
Congenital Adrenal hyperplasia Research, Education & Support Foundation (CARES Foundation, Inc.)
Congenital Hyperinsulinism International
COPD Foundation
CRPS Forum
Cure CMD
Cure HHT
Cure Sanfilippo Foundation
Cure VCP Disease
CURED Nfp
CureDuchenne
CureSHANK
Cystic Fibrosis Research, Inc.
Danny's Dose Alliance
debra of America
Dup15q Alliance
Dystonia Medical Research Foundation
EDSers United
Emily's Entourage
Epilepsy Foundation
Epilepsy Surgery Foundation
EveryLife Foundation for Rare Diseases
Fabry Support & Information Group
Fibrous Dysplasia Foundation
Fight Colorectal Cancer
FORCE: Facing Our Risk of Cancer Empowered
Foundation for Prader-Willi Research
Friedreich's Ataxia Research Alliance
Gaucher Community Alliance
GBS|CIDP Foundation International
Genetic Alliance
Global Allergy & Airways Patient Platform
Global Colon Cancer Association
Global Genes
Global Healthy Living Foundation
Global Liver Institute
Hannah's Hope Fund
HCU Network America
HealthHIV
HealthyWomen
Hereditary Disease Circle
HIV + Hepatitis Policy Institute

Hope For Dante'
Hope for Gus Foundation
HUNTER SYNDROME FOUNDATION
Hunter's Hope
Huntington's Disease Society of America
Hypersomnia Foundation
Hypothalamic Hamartomas
IGA Nephropathy Foundation of America
International Foundation for Autoimmune & Autoinflammatory Arthritis
International Foundation for Gastrointestinal Disorders
International Myeloma Foundation
International Pemphigus and Pemphigoid Foundation
Interstitial Cystitis Association
Kids With Heart National Assn for Children's Heart Disorders
Kindness Over Muscular Dystrophy
Klippel-Trenaunay Support Group
KrabbeConnect
Little Hercules Foundation
Little Miss Hannah Foundation
LUNGeivity Foundation
Lupus and Allied Diseases Association, Inc.
Lymphatic Education & Research Network
Mast Cell Hope
M-CM Network
Melanoma Research Foundation (MRF)
Men's Health Network
Mental Health America
MEPAN Foundation
METAvivor
Mila's Miracle Foundation
MLD Foundation
MTM-CNM Family Connection, Inc.
My City Med
Myositis Association
National Alopecia Areata Foundation
National Association of Nutrition and Aging Services Programs
National Ataxia Foundation
National Consumers League
National Fabry Disease Foundation
National Gaucher Foundation
National Grange
National MPS Society
National Pancreas Foundation
National Tay-Sachs & Allied Diseases Association (NTSAD)

National Urea Cycle Disorders Foundation
NBIA Disorders Association
NEC Society
NephCure Kidney International
NorCal CarciNET Community
One Rare
Orphan Disease Center at the University of Pennsylvania
Parent Project Muscular Dystrophy (PPMD)
Patient Services, Inc.
Pfeiffer's Health and Social Issues Awareness
Phelan-McDermid Syndrome Foundation
Piper's Kidney Beans Foundation
Pompe Alliance
Project Alive
Project Sleep
Propionic Acidemia Foundation
Pulmonary Fibrosis Foundation
Pulmonary Hypertension Association
PVNH Support & Awareness
PXE International
Rare and Undiagnosed Network (RUN)
Rare Army
Rare New England
RASopathies Network
Restless Legs Syndrome Foundation
RetireSafe
Sarcoidosis of Long Island
SCAD Alliance
Scleroderma Foundation
Second Wind Lung Transplant Association, Inc
Siegel Rare Neuroimmune Association
Sisters Network Inc.
Sjögren's Foundation
Spina Bifida Association
SSADH Association
Superficial Siderosis Research Alliance (SSRA)
Susan G. Komen
Syngap Research Fund, Inc.
T.E.A.M. 4 Travis
Taylor's Tale
Team Joseph
Team Sanfilippo Foundation
Texas Rare Alliance
The Brain Recovery Project: Childhood

The Familial Hypercholesterolemia Foundation
The Global Foundation for Peroxisomal Disorders
The International Foundation for CDKL5 Research
The Les Turner ALS Foundation
The Life Raft Group
The Marfan Foundation
The Oley Foundation
The OsteoPETrosis Society
The Oxalosis and Hyperoxaluria Foundation
Transplant Recipients International Organization
Tuberous Sclerosis Alliance
United Leukodystrophy Foundation
United Mitochondrial Disease Foundation
United Ostomy Associations of America
US Hereditary Angioedema Association
US Hereditary Angioedema Association
Usher Syndrome Coalition
We -CBJF
Wescoe Foundation for Pulmonary Fibrosis
White Sutton Syndrome Foundation
Wishes for Elliott
Zack Heger Foundation