



June 27, 2023

North Carolina Senate
Legislative Building
16 West Jones Street
Raleigh, NC 27601

Dear Honorable Members of the North Carolina Senate,

On behalf of the more than 1,100 people with cystic fibrosis (CF) in North Carolina, we write to express our support for HB 649 and HB 681. The first, HB 649, makes several important reforms to the prior authorization (PA) process to minimize the administrative burden PAs impose on patients and their providers, enhance efficiency of the process, promote transparency of PA requirements, and ensure PA determinations are rooted in evidence. The second, HB 681, would add North Carolina as a member of the Interstate Medical Licensure Compact (IMLC) to extend the reach of its physicians and improve access to telehealth services for patients with CF who get care across state lines. Together, these bills will improve access to care and treatments for people with CF while reducing administrative burdens on providers, allowing them to spend less time on paperwork and more time caring for their patients.

Cystic fibrosis is a life-threatening genetic disease that affects nearly 40,000 children and adults in the United States. CF causes the body to produce thick, sticky mucus that clogs the lungs and digestive system, which can lead to life-threatening infections. CF care is grounded in evidence-based clinical guidelines and as a complex, multi-system disease, CF requires an intensive treatment regimen including multiple medications. For people with CF, it is not uncommon to take seven therapies every day, and as many as twenty.¹ Many medications are taken year after year, and in most cases for life. While these therapies are helping people live longer, healthier lives, we also know patients often encounter barriers to accessing them.

HB 649 makes several important reforms to the prior authorization process

Prior authorizations are one of the obstacles people with CF must navigate when accessing care. These requirements can delay the start or continuation of needed treatments, which can lead to adverse health outcomes. Time consuming PA requirements can delay the start or continuation of needed treatments, which can lead to adverse health outcomes. In a 2022 survey by the American Medical Association, 94% of physicians reported that prior authorizations led to delays in necessary care for their patients whose treatment required PA and 80% reported that PAs have led to patients abandoning their treatment at some point.² Because CF is a progressive disease, patients who delay or forgo treatment—even for as little as a few days— face increased risk of lung exacerbations, costly hospitalizations, and potentially irreversible lung damage.³

PAs can also cause significant administrative burden for CF providers and are often redundant for medications that people with CF must take indefinitely to maintain their health. In a CF Foundation survey of CF care teams, 58 percent of providers reported spending 20 percent or more of their time on PAs in 2016. This arduous process diverts valuable time and resources away from direct patient care.

The Foundation appreciates that PA policies were adopted to ensure patients only receive medically necessary care, and we understand the challenge insurers face in managing medication utilization and cost. However, utilization management cannot come at the expense of delays in patient access to needed care. HB 649 provides

¹ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2680350/>

² <https://www.ama-assn.org/system/files/prior-authorization-survey.pdf>

³ Trimble AT, Donaldson SH. Ivacaftor withdrawal syndrome in cystic fibrosis patients with the G551D mutation. *J Cyst Fibros*. 2018 Mar;17(2): e13-e16. doi: 10.1016/j.jcf.2017.09.006. Epub 2017 Oct 24. PMID: 29079142.

an opportunity to make prior authorization processes more transparent, efficient, and evidence-based, allowing for timely access to appropriate treatments. We appreciate North Carolina's attention to this issue and support the following provisions in HB 649:

Medications for Chronic Diseases: Recognizing that patients with CF and other lifelong, chronic diseases take the same drugs for most of their lives, we appreciate that HB 649 exempts drugs and therapies used to treat chronic and long-term care conditions from repeat authorizations and requires insurers to honor a prior authorization approval for the duration of the treatment. Eliminating unnecessary repeat authorizations will help promote immediate and consistent access to life-saving therapies for people with CF, and significantly reduce administrative burden for CF care teams.

Gold Carding: To further reduce administrative burden and delays in care, HB 649 exempts providers from prior authorization requirements if 80 percent of their requests were approved in the preceding 12 months, a practice known as gold carding. Once a provider obtains an exemption, they would be exempt from having to request a PA for that healthcare service for at least the next year. Because cystic fibrosis requires highly specialized care and treatment, most people with CF receive care at a CF Foundation-accredited care center which provide quality, specialized CF care that is based in clinical guidelines. If members of a CF care team received an exemption, that care center could spend more time on patient care instead of paperwork and, most importantly, people with CF could avoid delays in care.

Response Times and Continuity of Care: HB 649 places time limits for health plans to respond to all prior authorization requests, thereby ensuring timely access to treatments. Also included in the bill is a continuity of care provision that protects patients from experiencing care delays when there are changes in coverage or when patients switch health plans. Gaps in therapy put people with CF at increased risk of costly hospitalizations and negative health outcomes. We support efforts to reduce delays in care and ensure people have timely access to their necessary medications.

Transparency for Prior Authorization Requirements: The CF Foundation applauds the provisions of HB 649 to increase transparency for prior authorizations, specifically the intent to require insurers to maintain a complete list of services that require PA, publicly share data on approvals and denials, and mandate PA requirements and criteria are easily accessible and clearly articulated. People with CF take many medications every day, many of which require PAs. Each additional PA can further exacerbate the administrative burden on both people with CF and care teams as they navigate the criteria required to obtain these medications. Increasing the availability of information on PA requirements and processes at the point-of-care will help reduce administrative burden and streamline the process for care teams.

Evidence-Based Review: One of the purposes of PA is to verify the clinical appropriateness of a service, so it is crucial that insurers use evidence-based criteria when developing PA requirements. CF treatments have very clear indications established by the Food and Drug Administration and it is essential that PA criteria reflect the data and label approval. HB 649 requires insurers to review their PA criteria annually and ensure it reflects current medical and scientific evidence. Additionally, PA denials must be made by a medical doctor who specializes in managing the medical condition or has experience providing the requested service.

HB 681 supports access to telehealth care for people living with CF

The Cystic Fibrosis Foundation accredits the more than 130 care centers in the United States — including 10 programs in North Carolina — and supports the development of CF clinical practice guidelines. Because CF requires highly specialized care and treatment, most people with CF receive care at one of these accredited CF care centers, which provide multidisciplinary care in accordance with systematically reviewed, data-driven clinical practice guidelines. The CF Foundation's care center network combines clinical research with medical care best practices and has been cited by the National Institutes of Health as a model for effective and efficient health care delivery for a chronic disease. This care delivery model has led to longer, more fulfilling lives for people living with CF.

The IMLC helps facilitate telehealth services for some people with CF who rely on out-of-state care centers and struggle to see their established providers. People living with CF may seek care across state lines for a variety of reasons, including geographic proximity or access to specialists with expertise in their particular comorbidities or disease state. For example, those who culture certain bacteria or are post-transplant may need to travel out-of-state to get appropriate care. Extending the reach of specialized physicians through licensure is an important tool to make remote care more accessible.

The IMLC will improve access to telemedicine services for CF patients who get care across state lines by streamlining the administrative aspects of physician licensing in participating states. Established in 2017, the IMLC was designed to facilitate the delivery of telemedicine while preserving state regulations of medical practice. Physicians licensed in a participating state can use the compact to obtain additional licenses in other participating states. Physicians do not need to fill out separate paperwork or provide additional fingerprints in each state, easing administrative burdens to help physicians reach more patients while also maintaining state medical boards' authority to regulate the practice of medicine and take disciplinary action as needed in their state. CF physicians report that burdensome administrative processes are a barrier to seeking licensure in other states and may prevent them from providing telehealth services to their out-of-state patients. Joining the IMLC will streamline the process for these physicians to apply for other state licenses and ensure continuity of care for their out-of-state patients.

The CF Foundation and the undersigned North Carolina CF care center directors urge you to support HB 649 and HB 681. By supporting these bills, you will help reduce administrative burdens on providers as well as ensure continued access to lifesaving treatments and quality, specialty care for people with CF. We appreciate your attention to these important issues for the CF community in North Carolina.

Sincerely,

Mary B. Dwight



Chief Policy & Advocacy Officer
Senior Vice President, Policy & Advocacy
Cystic Fibrosis Foundation

Shatha W. Yousef, MD

Director, Children's Cystic Fibrosis Center
Duke University Medical Center
Durham, NC

Holly C. Hanes, MD

Director, Pediatric Cystic Fibrosis Care Center
Atrium Health Wake Forest Baptist
Winston-Salem, NC

Elisabeth Dellon, MD, MPH

Co-Director, Pediatric Cystic Fibrosis Care Center
University of North Carolina at Chapel Hill
Chapel Hill, NC

Scott Donaldson, MD

Hubert E. Hatcher Family Distinguished Professor of Medicine
Division of Pulmonary and Critical Care Medicine
Co-Director, Adult Cystic Fibrosis Care Center
University of North Carolina at Chapel Hill
Chapel Hill, NC

Daniel K. Howard, MD

Atrium Health Adult Medical Specialties
Specialty Medical Director, Respiratory Health
Co-Director Atrium Health Adult CF Program
Medical Director, Pulmonary Rehabilitation at Kenilworth
Jan and Ed Brown Center for Pulmonary Medicine
Charlotte, NC

Dennis Schellhase, MD

Center Director, Atrium Health Cystic Fibrosis Program
Program Director, Levine Children's Cystic Fibrosis Program
Levine Children's Specialty Center, Atrium Health
Charlotte, NC