Alone we are rare. Together we are strong.®

November 5, 2026

North Carolina Department of Health and Human Services
NC Medicaid

Re: National Organization for Rare Disorders Comments on NC Medicaid Proposed Medical Frailty Policies

Dear Secretary Sangvai, Deputy Secretary Bush, and Dedicated Staff,

The National Organization for Rare Disorders (NORD®), on behalf of the approximately 1-in-10 North Carolinians with a rare disease, appreciates the opportunity to submit comments on the NC Department of Health and Human Services draft H.R.1 medical frailty exclusions policy, code lists, provider attestation form, and the webpage information.

For more than 40 years, NORD has served as the leading national patient advocacy organization dedicated to individuals with rare diseases, defined federally in the Orphan Drug Act as any condition affecting 200,000 or fewer Americans[i], and the organizations that serve them. With more than 355 patient organization members, NORD works to improve the health and well-being of people with rare diseases by driving advances in care, research, and policy. We believe that all individuals with a rare disease should have access to high quality, affordable health care that is best suited to meet their medical needs.

The Unique Risk to People with Rare Diseases

Rare disease affects fewer than 200,000 people per condition yet collectively impacts approximately 30 million – one in ten – Americans[ii]. For many of these individuals who have complex health care needs and may find their lives and their families' lives upended by the debilitating nature of their conditions, Medicaid is often the only pathway to care. Analysis of national hospital discharge data found that public payers, Medicaid and Medicare, covered more than 70% of adult rare disease inpatient stays; among children hospitalized with a rare disease, Medicaid alone was the primary payer for more than half of all visits (50.1%).[iii] The burden falls most heavily on those with the fewest options: among rare disease patients from underrepresented communities, individuals were three times more likely to report Medicaid as their primary insurance[iv].

Rare disease patients face substantial structural barriers to medical frailty recognition. While more than 10,000 rare diseases are known, only approximately 500 have specific ICD-10 diagnostic codes. Most are categorized under broad or nonspecific codes, making it difficult for individuals to demonstrate eligibility through diagnosis-based verification alone. With fewer than 5% of rare diseases having an FDA-approved treatment, access to care frequently includes participation in clinical trials, specialized treatment centers, and evolving care models. Medical expertise is often limited to a small number of providers nationwide, and rare disease patients often endure diagnostic journeys averaging 5–7 years before receiving a definitive diagnosis, which further lessens their ability to be identified by ICD-based criteria[v].

NORD recognizes the complexity of implementing the federal community engagement requirements outlined in H.R.1 §71119. Our comments focus on practical steps DHHS can take to minimize unintended

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coverage losses among eligible individuals, particularly people with rare diseases, while meeting federal requirements. Our detailed comments are as follows:

Engage Rare Disease Clinical Experts, Patients, and Caregivers in Design

NORD understands that on October 29, 2026, the Massachusetts federal district court vacated and set aside the portion of the CMS interim final rule's medical frailty definition requiring that the medical condition "significantly impairs" an individual's ability to comply with the community engagement requirements. The court also enjoined the federal government from enforcing that standard against the plaintiff states, which include North Carolina.

As NC Medicaid revises its medical frailty exclusions policy, code lists, provider attestation form, and webpage information, NORD respectfully recommends NC Medicaid establish a process for engaging clinical and other rare disease experts as well as rare disease patients and families in its development, review, and maintenance of its medically frail conditions list and related beneficiary- and provider-facing materials. This will help ensure that these processes and materials adequately account for the unique challenges rare disease patients face. Continuing to seek feedback on an ongoing basis, including after implementation has commenced, will help identify gaps in the identification process and opportunities to reduce administrative coverage loss.

North Carolina Rare Disease Centers of Excellence (RDCoE)
North Carolina's Rare Disease Centers of Excellence: Atrium Health Rare Disease Center and Duke Health Rare Disease Center, are a valuable resource for this purpose. These specialists can help identify conditions and codes that may be missing from a proposed list, evaluate whether conditions are appropriately assigned to their tiers, review provider- and beneficiary-facing materials, and identify circumstances where a diagnosis may not adequately convey the seriousness and complexity of someone's condition.

North Carolina Rare Disease Advisory Council (RDAC)
The NC RDAC, now housed in DHHS, has several statutory responsibilities that include advising the Governor, the DHHS Secretary, and the General Assembly on the identification of policy issues related to rare diseases and the advancement of policy initiatives related to rare diseases at the State and federal levels. Members have a range of experience and expertise and include rare disease physicians, researchers, patients, caregivers, a patient organization representative, pharmacists, genetic counselors, and other stakeholders.

Other states are finding value in collaborating across Medicaid and the RDAC to plan for work requirements implementation. For example, Utah's Rare Disease Advisory Council (RDAC) is working with Utah Medicaid to identify rare conditions that should be considered for inclusion on the state's medical frailty conditions list, helping ensure that individuals with rare diseases are appropriately considered for the medical frailty exclusion.

NORD offers the following model language that can be used in NC Medicaid's policy materials to help support opportunities for patients, caregivers, and the NC RDAC to provide input. This language is also applicable to and can be adapted for engagement with the NC MAC and BAC:

Developing a List of Conditions That Meet Medical Frailty Criteria – RDAC Consultation
"When developing a list of diseases, diagnoses, disorders or other health conditions for the purpose of defining medically frailty pursuant to Title 42 CFR Section 435.555(c)(5) (ii) and Section 1902(xx) of the Social Security Act, NC Medicaid shall seek input from the NC RDAC to identify rare and complex conditions that meet the criteria outlined in Title 42 CFR Section 435.555(c)(5)(i)(E).

a. *NC Medicaid may consult with the NC RDAC whenever it seeks to add to this list. It shall not remove a disease, diagnosis, or condition from this list unless it has provided the NC RDAC no fewer than 30 days to review and comment on the proposed removal, and has considered any comments received."*

System Design and Governance – RDAC Consultation and Engagement
"NC Medicaid shall consult the NC RDAC on eligibility system and notice design as it affects individuals with rare and complex conditions, including plain-language and accessibility review of forms, and shall provide the RDAC a reasonable opportunity to review and comment on proposed system and notice designs before they are finalized."

North Carolina Medicaid Advisory Committee and Medicaid Beneficiary Advisory Council (MAC/BAC)
North Carolina advisory bodies such as the MAC and BAC can provide important perspectives on these policies and public-facing materials as well. These advisory bodies can also help identify existing resources and avenues for support for patients and caregivers to prevent loss of coverage and to develop plans for targeted outreach prior to implementation. NORD also encourages engaging umbrella organizations and disease-specific patient advocacy organizations, not just individual patients, to help identify and recruit rare disease patients and caregivers, ensuring representation is broad and not limited to those already connected to formal advocacy networks.

NORD offers the following model language that can be used in NC Medicaid's policy materials to help support input within the MAC and BAC from individuals with rare disease experience and expertise:

> *"NC Medicaid shall amend the bylaws of the state's Medicaid Advisory Committee (MAC) or Beneficiary Advisory Council (BAC) to include a seat for NC RDAC or rare disease patient representation."*

NORD is prepared to support in any way that would be helpful, including providing policy expertise to inform RDAC recommendations, or helping connect NC Medicaid with rare disease specialists, patient organizations, and rare disease patients and caregivers who may be interested in joining the BAC or otherwise providing feedback.

Consider Applying for Good Faith Waiver to Use Full Potential Implementation Timeline

With the need to now re-adjust implementation plans related to medical frailty and the implementation deadline less than two months away, we recommend considering applying for a good faith waiver to ensure NC Medicaid has as much time as possible to ensure a strong medical frailty policy, processes, and accompanying public materials. particularly given the complexity of identifying and appropriately exempting individuals with rare diseases.

NORD also offers the following model language for use in NC Medicaid's policy materials to support use of the implementation timeline as well as providing for repeal and restoration of coverage if the federal mandate is no longer in effect in the future:

Utilization of Full Implementation Period & Immediate Repeal Upon Federal Action

1. *Effective no sooner than January 1, 2027, NC Medicaid shall implement work or community engagement requirements set forth in Section 1396a(xx) of Title 42 of the United States Code (Section 71119 of federal House Resolution 1 (Public Law 119-21)) to ensure that all eligible applicants and beneficiaries obtain and maintain coverage in ways that are least administratively burdensome to applicants and beneficiaries.*
2. *All community engagement requirements established within this State pursuant to H.R.1 §71119(A)(xx), shall cease to be operative and are hereby repealed upon the effective date of any federal law, regulation, or federal court order of national applicability that:*
    a. *renders compliance with community engagement requirements optional for states; or*
    b. *otherwise eliminates the federal mandate requiring states to implement community engagement requirements as a condition of Medicaid eligibility.*
3. *Upon such federal action, NC Medicaid shall immediately cease enforcement of community engagement requirements and shall restore coverage to any individual whose eligibility was affected solely by noncompliance with such requirements, without requiring a new application.*
    a. *The state shall provide such individuals notice of the restoration of their coverage. Such notice shall include the effective date of their coverage period and the date of their next renewal.*

Establish a Process for Considering Individuals with Unlisted Conditions and Updating Conditions Lists

NORD recommends that NC Medicaid establish a transparent process for reviewing and updating its medically frail conditions and codes lists and ensuring that individuals whose conditions are not included can request consideration for the medical frailty exclusion.

Under the draft policy, Tier 1 conditions will be identified through existing Medicaid data while individuals with Tier 2 conditions can establish eligibility through additional information submitted in the provider attestation form. However, the proposed materials do not explain how individuals with conditions that do not appear on either tier but that may meet the statutory medical frailty criteria can be reviewed for eligibility.

This creates particular concern for people with rare diseases. As noted above, it can take years for rare disease patients to receive a diagnosis, and for those that have one, many rare diseases lack specific diagnosis codes. Some rare disease patients live with multiple medical conditions that only collectively establish a serious or complex medical condition. Because there are so few providers nationwide that specialize in rare conditions, it can be difficult for patients to see providers and access documentation frequently. As a result, it is likely that many rare disease patients will fall under a Tier 2 condition or not fall under a conditions list at all, creating additional administrative hurdles that rare disease patients may be unable to meet, and increasing the risk of losing access to Medicaid coverage despite being eligible.

CMS's most recent and detailed medical frailty information, *Implementing Medical Frailty Under Community Engagement (Section 71119 of WFTC Legislation)*[vi], provides an example of a tiered

identification framework that includes a third tier for individuals whose medical frailty cannot be assessed based on the information available through the first two tiers. Under this example, such cases would trigger a manual individualized review, during which additional documentation may be requested. The presentation reinforces the statute and interim final rule in noting that states must have reasonable processes and criteria in place for individuals to request consideration for the medical frailty exclusion if an individual does not have a condition on the list(s), and that a states' conditions list(s) is intended to be used to help identify individuals who may qualify for medical frailty, not serve as an exhaustive list that precludes consideration of individuals with other qualifying medical conditions.

NORD therefore recommends that NC Medicaid establish and clearly communicate an individualized review pathway for individuals whose conditions are not represented on either tier. NC Medicaid should explain how individuals and providers can request review, what types of medical information or documentation may be submitted, how the state will evaluate requests, and the timeframe within which individuals can expect a determination. Individuals should be able to pursue this review without first having to secure the addition of their diagnosis or code to the state's conditions lists.

Consider utilizing the NORD Rare Disease Database

NORD also encourages NC Medicaid to consider available rare disease resources, including NORD's Rare Disease Database, when evaluating conditions that are not readily identifiable through existing diagnosis codes. NORD's Rare Disease Database is the largest continuously updated database of rare diseases available; over 10,200 conditions built with the Monarch Initiative (MONDO), Orphanet, Online Mendelian Inheritance in Man (OMIM), and the NIH Genetic and Rare Disease Information Center (GARD). Importantly, the NORD database is more comprehensive than any single federal database currently available to states. GARD's public-facing website represents a subset of its larger MONDO-derived list, and many conditions, particularly those without ICD-10 codes, are absent from resources states would otherwise consult.

NORD offers the following model language that can be used in NC Medicaid's policy materials to help incorporate rare disease information as well as clinical trial consideration and permanent or stable conditions into medical frailty processes, if allowable by federal law and CMS guidance:

> ***The NORD Rare Disease Database as a Resource for Medical Frailty Determinations***
> *NC Medicaid's verification plan required under 42 C.F.R. Section 435.557 shall include the NORD Rare Disease Database as a tool to identify medically frail patients.*
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> ***The NORD Rare Disease Database as a Resource for Medical Reviewers Downstream***
> *NC Medicaid shall integrate the NORD® Rare Disease Database in internal policy manuals and eligibility worker guidance as a tool for identifying rare and complex conditions, making medical frailty determinations, and informing which specific diagnosis and procedure codes to add to the state's medically frail conditions list.*
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> ***Clinical Trial Participation as an Indicator of a "Serious or Complex Medical Condition" and Permanent & Stable Exemptions for Permanent & Stable Conditions***
> *1. Clinical trial participation shall be considered an indicator of a "serious or complex medical condition" under the medically frail exclusion as described under 42 CFR Section 435.555(c)(5)(i)(E) if and to the extent allowable under then-current federal law and CMS guidance.*
> *2. NC Medicaid shall grant permanent medical frailty exemptions for individuals whose conditions are lifelong, degenerative, terminal, or otherwise permanent and unlikely to improve,*

and shall not require re-documentation of such status once established, if and to the extent allowable under then-current federal law and CMS guidance.

NORD's database is a reference tool that states can include in their verification plans and reviewers can use to better understand a rare condition's clinical severity and treatment requirements to support individualized medical frailty determinations. NORD would welcome the opportunity to discuss how this resource could support NC Medicaid's efforts to ensure that these individuals receive fair and consistent consideration regardless of the rarity of their diagnosis.

Conclusion

For the approximately 1-in-10 North Carolinians living with a rare disease and the caregivers who support them, Medicaid is a lifeline, not only for access to care, but for the stability required to manage complex and often lifelong conditions, and to remain engaged in the research that rare disease progress depends on.

NORD understands that implementation of H.R.1 is a complex undertaking, particularly following the federal district court's recent ruling. By creating a pathway for individualized medical frailty review, establishing a clear process for individuals to request consideration for medical frailty eligibility when that condition is not currently on either of the conditions list, and engaging directly with clinical experts, patients, and caregivers, NC Medicaid can ensure coverage is preserved for those who qualify. We appreciate the opportunity to provide these recommendations and welcome the opportunity to serve as a resource as NC Medicaid refines and implements these policies.

Thank you for your service to the people of North Carolina and for your consideration. For questions or more information, please contact Gretchen Frank at gfrank@rarediseases.org.

Sincerely,



Gretchen Frank

CC:
Kathryn Lowell, *Executive Vice President,* National Organization for Rare Disorders
Carolyn G Sheridan, MPH, *Associate Director of State Policy,* National Organization for Rare Disorders

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[i] 21 U.S.C. § 360bb, available at *Cornell Legal Information Institute*, https://www.law.cornell.edu/uscode/text/21/360bb
[ii] Rare Diseases at FDA, https://www.fda.gov/patients/rare-diseases-fda
[iii] Genetics in Medicine (2021), https://www.gimjournal.org/article/S1098-3600(21)05167-4/fulltext
[iv] NORD/RDDC. "Inequities in the Rare Disease Community," June 2024, p. 9 and table 8. https://rarediseases.org/wp-content/uploads/2024/08/RDDC-Survey-Report.pdf
[v] *Rare Disease Facts and Statistics: Rare Disease at a Glance*, NORD, https://rarediseases.org/understanding-rare-disease/rare-disease-facts-and-statistics/
[vi] *Implementing Medical Frailty Under Community Engagement (Section 71119 of WFTC Legislation),* CMS, https://www.medicaid.gov/resources-for-states/working-families-tax-cut-legislation/community-engagement/ImplementingMedicalFrailtyDeck.pdf