CMS-2026-2047-0002 Medicaid Community Engagement Requirement for Certain Individuals

Table of Contents

Comment Summary

The Myalgic Encephalomyelitis Action Network (#MEAction) submits this comment in reference to the new guidance to States on the "Medicaid Program: Community Engagement Requirement for Certain Individuals" (CMS-2026-2047-0002).

We object to this Interim Final Rule as it is currently written. It does not reflect the realities of people living with myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS), Long COVID, and other infection-associated chronic conditions and illnesses (IACCIs).

These regulations need to be appropriately revised so that individuals with IACCIs do not have their essential health care procedurally terminated, simply because they struggle to navigate the process for documenting and verifying their status as individuals specifically excluded from the IFR's community engagement requirements on the basis of their serious or complex medical conditions that have resulted in their medical frailty and special medical needs.

Broadly, we urge you to make critical revisions to the following sections of the IFR:

1. the definition of specified excluded individuals who are medically frail at §435.554(c)(5)(i) with serious or complex medical conditions;

2. the procedures for verifying exclusion from the community engagement requirement on the basis of medical frailty at §435.557(f); and

3. the noncompliance procedures and State responsibilities at §435.558 for individuals who fail to demonstrate meeting the criteria for a specified excluded individual on the basis of medical frailty.

Failure to take into consideration the specific medical needs and challenges to accessing care of over 20 million Americans affected by IACCIs[1], which we will further elaborate on in this comment, will result in worsening health outcomes for patients, increased downstream Medicaid costs to tax payers, and it will inhibit the stated policy goal of furthering community engagement.

Infection-Associated Chronic Conditions and Illnesses

The IFR's lacks a basic understanding of the experiences of individuals with infection-associated chronic conditions and illnesses (IACCI)[2] which has resulted in a problematic regulatory definition of medical frailty and an inadequate process for verifying individuals' exclusions from community engagement requirements. This IFR does not engage with any of the evidence, examples, or recommendations that MEAction provided to CMS leadership earlier this year.[3] But it also lacks any engagement with the information about IACCIs that is available in National Academies reports or publications by IACCI experts working at HHS and CDC which we outline below.

In May 2026 the Office of the U.S. Surgeon General announced "Millions of Americans live with infection-associated chronic conditions and illnesses, including long COVID, ME/CFS, and Lyme disease–associated chronic symptoms; conditions that are often debilitating, misunderstood, and under-recognized."[4] OSG shared a recent Clinical Infectious Diseases viewpoint by Captain Iskander and Dr. Haridopolos that called for making these "invisible illnesses" visible through patient-centered care, stronger surveillance, multidisciplinary management, and continued research investment.[5]

Iskander and Haridopolos acknowledge that "Patients with diagnosed or suspected myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS) have long expressed concerns that their

---

[1] John K Iskander, Stephanie Haridopolos, Making Invisible Illnesses Visible: Recognizing and Responding to Infection-Associated Chronic Conditions, *Clinical Infectious Diseases*, 2026;, ciag240, Page 3, https://doi.org/10.1093/cid/ciag240

[2] The terms infection-associated chronic conditions (IACC), infection-associated chronic illnesses (IACI), or infection-associated chronic conditions and illnesses (IACCI) have been variously used in recent CDC, HHS and NASEM contexts.

[3] #MEAction. Letter to CMS Administrator Mehmet Oz re: Medicaid community engagement requirements exemptions for medically frail individuals with ME/CFS, Long COVID, and other infection-associated chronic conditions. April 17, 2026. https://www.meaction.net/post/meaction-sends-letter-to-dr-oz-urging-for-medicaid-protection

[4] https://x.com/Surgeon_General/status/2055400493128798234

[5] Iskander and Haridopolos (2026)

health status was not accorded sufficient clinical and policy scrutiny." They argue that the documented disease burden is sufficient justification for ongoing investment across multiple areas of medicine, research and public health. They cite as "grounds for optimism" the "new data and emphasis on IACCIs from the Centers for Disease Control and Prevention (CDC)" and the "high priority placed on chronic disease control by the current leadership of the US Department of Health and Human Services (HHS)".

However, the regulations CMS has proposed regarding exclusions from Medicaid community engagement requirements for medically frail individuals with serious or complex medical conditions do not evidence a similar understanding of the issues faced by people with IACCIs and the impact these regulations will have on them.

Last year in the CDC publication Emerging Infectious Diseases, Dr. Anthony Fiore, former chief of Epidemiology Research and Innovations Branch at the CDC, warned in an a recent article entitled "Progress Toward Understanding Infection-Associated Chronic Conditions and Illnesses" that not only do "IACCIs cause marked disruption to a patient's ability to return to work or school or to resume their life as it was before the inciting infection," but the situation is further complicated because "Patients suffering with IACCIs often receive misdiagnoses or become stigmatized, both of which impede potentially beneficial clinical management strategies. Without an understanding of pathophysiology, diagnosis, treatment, and care for patients with IACCIs, healthcare providers will continue struggling to provide patients with accurate diagnoses and potentially effective treatment and support."[6]

Dr. Elizabeth Unger, former Chief of the Chronic Viral Disease Branch at the CDC, has similarly described the stark situation common to individuals with Long COVID, ME/CFS and other infection-associated chronic conditions "who had no abnormalities on routine tests but were crippled by systemic symptoms including cognitive impairment, severe fatigue, sleep problems, and illness relapse from minimal activity that could have been tolerated prior to illness (i.e., post-exertional malaise)."[7] Individuals with IACCs have "faced disbelief, stigma, and denial of support from health care providers, social support services, and employers. Some were even abandoned by families and friends… [this] needs to be a call to action to marshal the multi-disciplinary resources needed to address these neglected conditions."[8]

Unger soberingly concludes "Despite the many years that it has been recognized that infections can have multiple long term-impacts on health, we are still unraveling the extent of the complexity of the intersection of genetics, environment, and infections. We need to be realistic about the speed at which we can expect progress in diagnostics and interventions. A great deal of humility is required as we move forward, as there is so much that we don't understand. This is

[6] Fiore, A. E. (2025). Progress Toward Understanding Infection-Associated Chronic Conditions and Illnesses. Emerging Infectious Diseases, 31(14), 1-2. https://doi.org/10.3201/eid3114.251187.
[7] Unger E. R. (2025). Long COVID as an Infection-Associated Chronic Condition: Implications. American journal of health promotion : AJHP, 39(6), 962. https://doi.org/10.1177/08901171241308066b
[8] Ibid., 961.

particularly important for those providing healthcare, as patients need to be supported and believed, even when there are no definitive answers."[9]

The significant disease burden of IACCIs and the urgent need for improvements to patient diagnosis and care along with accelerated research have been detailed across various National Academies reports for ME/CFS (2015), Long COVID (2024), Lyme disease–associated chronic symptoms (2025), and infection-associated chronic conditions more generally (2024, 2004).[10] While questions remain about the pathophysiology of IACCIs, the seriousness and complexity of managing these medical conditions has been repeatedly documented, as is the harm and debilitation patients suffer when adequate support is not made available.

In the IFR, CMS references multiple times the 1999 IOM report "Definition of Serious and Complex Medical Conditions." That report points out that "Serious and complex medical conditions should reflect the characteristics of the management of the condition rather than some inherent biological complexity… the various meanings of serious and complex will have more to do with illness and disability management than with underlying biology."[11]

Captain Iskander and Dr. Haridopolos specifically called out the opportunity to strengthen clinical practice through use of the new add-on code CMS introduced in 2024 that would "recognize the time and resources needed to provide comprehensive longitudinal care management for individuals with complex chronic conditions. Primary care physicians can use this code (G2211) when they help patients manage a serious or complex condition such as an IACCI."[12] That code, however, is a Medicare payment mechanism that many State Medicaid programs have not adopted, leaving it largely unavailable to the Medicaid population with IACCIs.

This CMS IFR never addresses how the community engagement requirements can be feasibly implemented for individuals with a serious or complex condition such as IACCIs. IACCIs lack the advances in treatment that would enable these conditions to be reliably well-managed which

---

[9] Ibid., 964.

[10] National Academies of Sciences, Engineering, and Medicine. 2025. *Charting a Path Toward New Treatments for Lyme Infection-Associated Chronic Illnesses.* Washington, DC: The National Academies Press. https://doi.org/10.17226/28578; National Academies of Sciences, Engineering, and Medicine. 2024. *A Long COVID Definition: A Chronic, Systemic Disease State with Profound Consequences.* Washington, DC: The National Academies Press. https://doi.org/10.17226/27768; National Academies of Sciences, Engineering, and Medicine. 2024. *Toward a Common Research Agenda in Infection-Associated Chronic Illnesses: Proceedings of a Workshop.* Washington, DC: The National Academies Press. https://doi.org/10.17226/27462; Institute of Medicine. 2015. *Beyond Myalgic Encephalomyelitis/Chronic Fatigue Syndrome: Redefining an Illness.* Washington, DC: The National Academies Press. https://doi.org/10.17226/19012; Institute of Medicine. 2004. *The Infectious Etiology of Chronic Diseases: Defining the Relationship, Enhancing the Research, and Mitigating the Effects: Workshop Summary.* Washington, DC: The National Academies Press. https://doi.org/10.17226/11026

[11] Institute of Medicine (US) Committee on Serious and Complex Medical Conditions; Chrvala CA, Sharfstein S, editors. Definition of Serious and Complex Medical Conditions. Washington (DC): National Academies Press (US); 1999. 1, Introduction. Available from: https://www.ncbi.nlm.nih.gov/books/NBK224968/

[12]

significantly impacts individuals' ability to comply with community engagement requirements. Individuals with IACCIs face entrenched stigma, misdiagnosis, lack of FDA-approved treatments, and physicians who are often not reimbursed for the additional work and extended visit time needed to provide adequate chronic condition management. This puts individuals with IACCIs inherently at risk that the State will not be able to verify their exclusion from community engagement requirements on the basis of medical frailty, especially after the State can no longer accept an individual's own statement self-reporting their medical frailty.

"But you don't look sick" are the words every patient with an IACCI dreads hearing from a healthcare provider uninformed about the proper clinical management of IACCI symptoms. This IFR could result in IACCI stigma being weaponized against patients, except instead of this stigma resulting in a delay or denial of IACCI-informed care, the individual will risk having their entire healthcare coverage terminated. If as experts and government sources widely acknowledge that the current healthcare system does not adequately care for IACCI patients then it should also be acknowledged that this same healthcare system is unlikely to be able to reliably reverify the full symptom impairment of these patients every six-to-twelve months once their statement self-attestating to medical frailty is no longer allowed.

Individuals with IACCIs suffering from cognitive impairment, severe fatigue, sleep problems, and illness relapse from minimal activity cannot reasonably be expected to navigate alone the process of obtaining and submitting the documentation to prove their medical frailty to the State and keep their coverage. The IFR further exacerbates this problem by not allowing States to use medical frailty documentation from an IACCI specialist that is over 12 months old.

After outlining the above general issues facing individuals with IACCIs that the IFR does not adequately engage with, we next turn to the specific serious and complex medical condition of myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS). ME/CFS is a medical condition that deserves specific attention by CMS because it has:

1. a clinical diagnostic criteria established by a National Academies report that definitionally should be treated as a meeting the criteria for medically frailty,
2. a newly implemented ICD-10-CM code that State claims data is unlikely to initially identify or be familiar with,
3. a body of public health information and provider resources created by the CDC that addresses the misconceptions about the condition and the role activity limitation plays in symptom management

The medical frailty of ME/CFS

According to the Centers for Disease Control and Prevention, "myalgic encephalomyelitis/ chronic fatigue syndrome (ME/CFS) is a biological illness that affects many body parts. It causes severe fatigue not improved by rest, problems thinking and sleeping, dizziness, pain, and many other symptoms. People with ME/CFS may not look sick but can't do their normal

activities. ME/CFS may get worse after they do any activity -- physical or mental. This symptom is called post-exertional malaise (PEM). After they exert themselves, they may need to stay in bed for an extended time. About 1 in 4 people with ME/CFS are confined to bed at some point in their illness."[13] People with ME/CFS also have a lower quality of life on average than multiple sclerosis, chronic kidney failure, or congestive heart failure.[14]

A diagnosis of ME/CFS is a clinical determination of the presence of a medical condition that is by definition serious or complex. To be diagnosed with ME/CFS means an individual exhibits a pattern of specific symptoms that by definition must significantly impair that individual's ability to comply with Medicaid community engagement requirements.

In 2015 the Institute of Medicine (now known as the National Academy of Medicine) published diagnostic criteria for ME/CFS.[15] The CDC has adopted the IOM 2015 diagnostic criteria for ME/CFS and in 2022 the CDC's National Center for Healthcare Statistics added G93.32 as the diagnostic code for ME/CFS to the ICD-10-CM. CMS should issue guidance, and all State Medicaid agencies should implement procedures to ensure that new or existing Medicaid enrollees with a G93.32 diagnosis are exempted from any work requirements. At a minimum, CMS should specifically include ME/CFS in in the IFR preamble regarding the medically frail definition where it lists certain conditions that CMS believes it would be reasonable for States to consider as serious or complex.

According to CDC and IOM criteria a diagnosis of ME/CFS requires the presence of the following three symptoms (plus at least one of the two additional symptoms).[16] These are listed below to demonstrate how clearly incompatible they are with any work requirement and how a requirement to work would worsen an individual's ME/CFS symptoms.

The following three symptoms are all required for a ME/CFS diagnosis:

1. A substantial reduction or impairment in ability to engage in pre-illness levels of activity (occupational, educational, social, or personal life) that lasts for more than 6 months and is accompanied by fatigue that is often profound, of new onset (not life-long), not the result of ongoing or unusual excessive exertion, and not substantially alleviated by rest.

2. Post-exertional malaise (PEM) -- worsening of symptoms after physical, mental, or emotional exertion that would not have caused a problem before the illness. PEM often puts the patient in relapse that may last days, weeks, or even longer. For some patients,

---

[13] CDC. ME/CFS Basics. https://www.cdc.gov/me-cfs/about/index.html accessed 07/10/26.
[14] Falk Hvidberg M, Brinth LS, Olesen AV, Petersen KD, Ehlers L (2015) The Health-Related Quality of Life for Patients with Myalgic Encephalomyelitis / Chronic Fatigue Syndrome (ME/CFS). PLOS ONE 10(7): e0132421. https://doi.org/10.1371/journal.pone.0132421; Kingdon, C.C., Bowman, E.W., Curran, H. et al. Functional Status and Well-Being in People with Myalgic Encephalomyelitis/Chronic Fatigue Syndrome Compared with People with Multiple Sclerosis and Healthy Controls. PharmacoEconomics Open 2, 381–392 (2018). https://doi.org/10.1007/s41669-018-0071-6.
[15] Institute of Medicine. 2015. Beyond Myalgic Encephalomyelitis/Chronic Fatigue Syndrome: Redefining an Illness. Washington, DC: The National Academies Press. https://doi.org/10.17226/19012
[16] CDC. IOM 2015 Diagnostic Criteria.
https://www.cdc.gov/me-cfs/hcp/diagnosis/iom-2015-diagnostic-criteria-1.html

sensory overload (light and sound) can induce PEM. The symptoms typically get worse 12 to 48 hours after the activity or exposure and can last for days or even weeks. To be diagnosed with ME/CFS patients should have this symptom at least half of the time with moderate, substantial, or severe intensity.

3. Unrefreshing sleep -- patients with ME/CFS may not feel better or less tired after a full night's sleep. This may occur despite the absence of specific objective sleep alterations. To be diagnosed with ME/CFS patients should have this symptom at least half of the time with moderate, substantial, or severe intensity.

To be diagnosed with ME/CFS, patients must also have at least one of the symptoms below. These are in addition to the three required symptoms above.

4. Cognitive impairment -- problems with thinking, memory, executive function, and information processing. They also have attention deficit and impaired psychomotor functions. All can be exacerbated by exertion, effort, prolonged upright posture, stress, or time pressure. This may have serious consequences on a patient's ability to maintain a job or attend school full time. To be diagnosed with ME/CFS patients should have this symptom at least half of the time with moderate, substantial, or severe intensity.

5. Orthostatic intolerance -- a worsening of symptoms upon assuming and maintaining upright posture. This is measured by heart rate and blood pressure abnormalities during standing, bedside orthostatic vital signs, or head-up tilt testing. Symptoms including lightheadedness, fainting, increased fatigue, cognitive worsening, headaches, or nausea are worsened while upright (either standing or sitting). Symptoms are improved (though not necessarily fully resolved) with lying down.

Given this specific diagnostic criteria the only accurate way to understand a diagnosis of ME/CFS is to accept it as a clinical judgement that an individual is medically frail and should not be required to comply with an arbitrary standard of activity that may make their serious or complex medical condition worse.

The CDC has created specific resources to help healthcare providers better manage patient's post-exertional malaise (PEM), a hallmark symptom of ME/CFS. "Helping patients manage PEM should be one of the first actions healthcare providers take. One of the best options to minimize or prevent PEM is to help patients learn to keep all energy expenditures, physical, cognitive and emotional, within limits that can be tolerated by planning when and how to use their limited energy."[17] In a bolded section on harm reduction it further warns healthcare providers against recommending increased activity, which can be harmful, without taking precautions about PEM and it cites studies showing impaired aerobic energy metabolism in patients with ME/CFS. The CDC further warns that even activities of daily living can trigger PEM, and any activity recommendations must take into account a patient's individual energy limits (including the specific intensity, duration, and frequency of activity the patient can tolerate).

[17] Centers for Disease Control and Prevention. Managing Post-Exertional Malaise (PEM) in ME/CFS, Myalgic encephalomyelitis/chronic fatigue syndrome healthcare provider toolkit, https://www.cdc.gov/me-cfs/pdfs/toolkit/managing-pem_508.pdf

CMS's community engagement requirements are standardized to 80 hours a month of qualifying activities. This activity requirement cannot be reconciled with patient symptom management guidelines for a medical condition that is fundamentally based on activity limitation to prevent symptom flares. Even if an individual with ME/CFS performs 80 hours of activity in a given month the underlying medical frailty of their condition has not been eliminated. They still are significantly impaired in their ability to comply with the community engagement requirement because the proper management of their condition depends upon having the ability to drastically reduce activity whenever their symptoms flare (which can change from month to month, week to week, day to day, and even hour to hour).

The most straightforward interpretation of the medical frailty exclusion that Congress mandated from the community engagement requirement is that it should not be applied to disabled and chronically ill individuals who could be reasonably harmed by such a requirement. There is no medically safe way to withhold from an individual with ME/CFS the ability to limit their activity for symptom management purposes, including not complying with the community engagement requirement. There is no justifiable basis to conclude that Medicaid community engagement requirements won't have a negative impact on people with ME/CFS.

Self-attestation of medical frailty should not be sunset in 2028

The simplest and most robust way to identify people with ME/CFS, Long COVID, other infection-associated chronic conditions and illnesses for medical frailty exclusions from community engagement requirements is to allow people applying for or enrolled in Medicaid to self-identify that they have a serious or complex medical condition that meets exemption criteria. States should be permitted to accept this declaration as sufficient verification as permitted under federal law and consistent with current practices for other eligibility categories in many states.

We strongly object to the IFR at § 435.557(f)(1)(ii) limiting States to only be able to use an individual's self-attestation of medical frailty one time after January 1, 2028. It is not a reasonable assumption that requiring the State to reverify an individual's medical frailty through data or other documentation "will motivate individuals to access care" and that the beneficiary will necessarily be "able to receive covered services to address their health condition." All the evidence on individuals with IACCIs that we have summarized earlier in this comment demonstrates that it is extremely difficult for them to get access to care. No matter how "motivated" individuals with IACCIs may be they cannot control if their State Medicaid agency does not reimburse their primary care physicians for the time and resources needed to provide comprehensive longitudinal care management for their condition.

The 2015 Institute of Medicine report on ME/CFS estimated that up to 91% of ME/CFS cases may go undiagnosed and the time to diagnosis in 29% of cases is at least 5 years.[18] If States are prohibited using statements from individuals with ME/CFS and other IACCIs that self-attest

[18] Institute of Medicine. 2015.

to their own medical frailty then many of these individuals will be harmed by the high administrative burden CMS is setting for verification.

Ultimately, the difficulty of verifying serious or complex medical conditions such as IACCIs within the current healthcare system must be confronted. It is individuals with IACCIs themselves who are in the best position to communicate the extent of their medical frailty. If CMS is not willing to treat their self-reports of medical frailty as reliable, then CMS must acknowledge that higher standards of verification of medical frailty can only be achieved through greater time and resources. Improvements to the verification processes and standards for exclusions from community engagement requirements depend upon making improvements to care for medically frail individuals with IACCIs.

The IFR quotes multiple times from the 1999 Institute of Medicine report on defining serious and complex medical conditions in order to defend aspects of CMS' more restrictive definition of medical frailty, but it ignores the report's conclusion which is relevant to State approaches to both defining and verifying serious or complex medical conditions for medically frail exclusions from work requirements.

The IOM report concludes, "Health plans and [CMS] should also be aware of the challenges inherent in the process of data collection, management, analysis, and interpretation. The potential for errors and biases is present at each step and could result in misclassification of patients with serious and complex medical conditions. The collection of timely information that is of sufficient sensitivity and specificity to reduce the number of false-positive and false-negative classifications as serious and complex imposes significant burdens and will require allocation of adequate resources and professionally trained staff."[19] These challenges were so significant that the report's number one recommendation was that CMS should not establish an administrative definition for serious and complex medical conditions. Given that the Congressional legislation mandating new Medicaid community engagement requirements also made significant cuts to funding for State Medicaid programs, CMS should embrace a verification method for medical frailty that is aligned with the reality of current federal and state resource constraints. CMS should prioritize supporting individuals with IACCIs with accessible ways of reporting their medical frailty through self-attestation and minimize the administrative burdens on individuals and States.

Regulations will increase disability from IACCIs and increase downstream Medicaid costs to taxpayers

Individuals with IACCIs who the State is unable to determine are excluded from the community engagement requirements will either lose the flexibility to effectively manage their symptoms through activity limitation, or they will lose their health care coverage entirely. Earlier in this

[19] Institute of Medicine (US) Committee on Serious and Complex Medical Conditions; Chrvala CA, Sharfstein S, editors. Definition of Serious and Complex Medical Conditions. Washington (DC): National Academies Press (US); 1999. 1, Introduction. https://www.ncbi.nlm.nih.gov/books/NBK224968/

public comment we described in detail the symptoms of ME/CFS and the activity limitation strategies that are essential when there are no FDA-approved treatments for this condition. Loss of health coverage and access to medical care makes it hard for these individuals to manage their health conditions as well, which may also exacerbate their illnesses.

Worsening of ME/CFS severity has significant consequences. ME/CFS of “mild” severity is generally considered a 50% reduction in activity compared to before the onset of the illness, while “moderately” severe ME/CFS is when an individual is housebound for most of the time and only leaves the house after careful planning. When individuals with mild or moderate ME/CFS are unable to practice activity limitation strategies for symptom management their conditions may worsen leading to even greater disability and they may need to access more costly support and services from State Medicaid agencies. The potential increased burden on Medicaid’s Home and Community Based Services waivers programs and other Long-Term Services and Supports is significant. People with severe ME/CFS are mostly bedridden, while very severe ME/CFS manifests in completely bedridden, requiring assistance for basic needs and deprivation from sensory inputs such as sound, light, smell, and touch.

CDC clinical care guidance for patients with severe ME/CFS states, “These patients often cannot make office visits due to the severity of their symptoms. They require in-home assistance and management plans specifically adjusted to their needs by a coordinated care team of providers. Caregivers, who provide management and the majority of care for patients, often have substantial stress and may need additional support. The subset of severely ill ME/CFS patients who are completely bedbound requires special attention. They need in-home visits and phone/online check-ups, and a modified approach to activity management.”[20] Again, given the limited treatment options, and the harm to individuals’ functional capacity that can result from unmanaged post-exertional malaise, it is critical that all people with ME/CFS are excluded from community engagement requirements. These requirements not only present serious risks to individuals' health but they threaten to significantly raise costs to taxpayers when individuals with ME/CFS conditions worsen.

Regulations will disincentivize community engagement for individuals with IACCIs

Individuals with ME/CFS and other IACCIs face significant social isolation because of their debilitating symptoms and their inability to consistently engage in activities they were able to participate in before getting ill. The CDC specifically highlights the “anger, frustration, and despair” that can accompany living with the debilitation of ME/CFS.[21]

[20] CDC. ME/CFS Clinical Care for Severely Affected Patients. https://www.cdc.gov/me-cfs/hcp/clinical-care/me-cfs-clinical-care-for-severely-affected-patients.html
[21] Ibid.

CDC “Voice of the Patient” series contains numerous examples of people with ME/CFS struggling to live within their new limitations and still be supported by their families and friends.[22] HHS Health+ Long COVID report outlined an “opportunities framework” with recommendations for creating the “safe, responsive, and supportive conditions that enable people with Long COVID to more fully engage in the world around them.”[23] Requiring 80 hours a month of work, school, or volunteer activities from individuals with IACCIs will present a serious risk to their health. Individuals with IACCIs, whose symptoms may unpredictably fluctuate significantly, need the flexibility to engage in their communities when and how it aligns with managing their symptoms. If individuals are afraid episodic community engagement may be mistaken for a lack of medical frailty and threaten their status as specified excluded individuals, they will be disincentivized from participating in community engagement activities which is the exact opposite of the stated goal of this policy. Individuals with IACCIs need protections of their specified excluded status that are broad and clear so that they can be encouraged to engage their communities safely with no fear that their access to essential healthcare could be at risk.

Recommended Changes to the Interim Final Rule

To protect individuals with myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS) and other infection-associated chronic conditions and illnesses (IACCI) from being harmed by CMS’ interim final rule we urge the following changes be made.

There are a number of interpretative statements in the IFR about what medical frailty is, and how exclusion from community engagement requirements should be verified that we strongly disagree with and believe should be changed. Below we offer only a limited selection of recommended revisions that could most improve this rule and reduce harm to individuals with IACCIs even if other areas of this interim final rule remain unchanged. We appreciate review and consideration of each of these recommendations individually.

II.E.5.b. Medically frail definition

Revise the list of example conditions provided on page 33376, second column, of the federal register that CMS believes would be reasonable for States to consider as serious or complex to add “ME/CFS” or “infection-associated chronic conditions such as ME/CFS.”

This comment has provided detailed evidence for why ME/CFS must be considered a serious or complex medical condition, and the risk for stigma and misunderstanding about this condition to be perpetuated if CMS does not affirmatively clarify its support for the characterization provided by expert sources within HHS, CDC, and the National Academies.

[22] CDC. Voice of the Patient. https://www.cdc.gov/me-cfs/living-with/index.html#cdc_living_with_managing_popu-voice-of-the-patient
[23] HHS. Health+ Long COVID report. https://www.hhs.gov/sites/default/files/healthplus-long-covid-report.pdf

We also think it would be warranted to include other infection-associated chronic conditions in the example list which are commonly diagnosed in people with ME/CFS including Long COVID, Ehlers-Danlos syndrome; disorders of autonomic function, such as postural orthostatic tachycardia syndrome (POTS); and mast cell activation syndrome (MCAS), all of which have their own ICD codes.

II.I.7.e. Individuals who are medically frail

Withdraw the interpretation on page 33405, third column, of the federal register "States may not consider information older than 12 months when verifying medical frailty or other special medical needs, because older information may not reflect the individual's current condition."

This language is not found in the regulation and this narrow interpretation is unnecessary and particularly harmful to individuals with IACCIs who are more likely to have the state request additional information from them to verify their medical frailty. If they are able to obtain "documentation and other information" it is more likely to take them longer and come at a higher cost, especially if it is from IACCI specialists who are in limited supply. Documentation for a long-lasting chronic condition that is older than 12 months may provide important context and more directly address the extent of symptom impairment that States should be allowed to consider when verifying medical frailty, otherwise CMS risks setting a documentation standard that individuals with IACCIs find impossible to meet no matter how significant their impairment.

§435.554(c)(5)(i) Medically frail definition

Revise the definition of medical frailty on page 33472 of the federal register, second column, by removing the words "whose physical, mental, or other behavioral health condition significantly impairs the individual's ability to comply with the community engagement requirement in this subpart and is an individual".

Adding an additional test for functional capacity in addition to the requirement of being one of the five subcategories of medical frailty is overly administratively burdensome to individuals with IACCIs. Individuals with IACCIs disproportionately struggle to have their debilitating medical conditions recognized and treated by the current health care systems. These barriers in access to care will be mirrored in barriers for the State to accurately reflect their activity limitations. For too long individuals with IACCIs have been dismissed with the words "but you don't look sick." The current wording of the regulations put individuals at the same risk of the State inappropriately withholding health-critical exclusions from community engagement requirements.

If CMS chooses to not remove the language narrowing the definition of medical frailty that we strongly recommended striking, then as an alternative we urge CMS to at minimum add the modifier "consistent" to "ability to comply (e.g. "individual's consistent ability to comply with…") to more clearly communicate to States that individuals with an inconsistent functional capacity and episodic disability are still medically frail.

§435.557(f) Verification of medical frailty

Remove the limiting words "only once" from §435.557(f)(ii) about the use of statements or other information provided under penalty of perjury. Remove all wording in this subpart that prohibits ongoing use of self-attestation statements provided under penalty of perjury as information the State can use to verify medical frailty.

Individuals with IACCIs will have significant difficulty obtaining and submitting documentation to verify their medical frailty. This vulnerable, high-risk population needs to have the ability to self-report their medically frail status.

Remove the requirement to reverify medically frail status every 12 months at §435.557(f)(iii).

Individuals with IACCIs are at significant risk of inappropriately not receiving specified excluded individual status because of the difficulty of meeting the administrative burden of reverifying their medical frailty every year especially when they experience a change in their care team and have a poorly-educated healthcare provider who does not know how to effectively treat or assess their condition.

§435.558 Noncompliance procedures

Revise §435.558 noncompliance procedures subpart to include an alternative process for the medically frail as was done for the process of verifying compliance at § 435.557(b)(2).

Add the language "Except with respect to verifying an individual is a specified excluded individual on the basis of being medically frail or otherwise having special medical needs as defined at §435.554(c)(5)"

Under this alternative noncompliance procedures for the medically frail implement the following:

1) Where documentation from the individual is required consistent with § 435.557(f), provide the individual with a reasonable opportunity period of no fewer than 90 days from the date of the declaration to obtain and submit such documentation.

2) Extend the reasonable opportunity period if the agency determines that the individual is making a good faith effort to obtain necessary documentation or that the agency needs more time to verify the individual's status or to assist the individual, including where a physical, mental, or other health-related limitation, or the unavailability of a timely appointment with an appropriate health care practitioner, has prevented the individual from obtaining or submitting documentation.

3) Maintain reasonable processes and criteria, consistent with § 435.554(c)(5), for an individual to request consideration for the exclusion where documentation cannot be obtained within the reasonable opportunity period.

Individuals with IACCIs are disproportionately likely to be subject to noncompliance procedures not because they are not specified excluded individuals, but because they struggle with significant physical and cognitive limitations navigating administrative requirements unaided. To protect this vulnerable group they need to have a dedicated noncompliance process—as the IFR does with verification processes at § 435.557(f)—to ensure that incorrect administrative actions are not taken that endanger their health. They need additional time to submit information and the State agency needs administrative flexibility to continue to work with individuals who need additional time or have special circumstances where obtaining information is especially difficult.