



December 28, 2020

SUBMITTED ELECTRONICALLY VIA www.regulations.gov

The Honorable Alex M. Azar
Secretary
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

**RE: Regulatory Relief to Support Economic Recovery; Request for Information
(HHS-OS-2020-0016-0001)**

Dear Secretary Azar:

The undersigned members of the Coalition to Preserve Rehabilitation (CPR) Steering Committee appreciate the opportunity to comment on the Department of Health and Human Services' (HHS) Request for Information (RFI) on Regulatory Relief to Support Economic Recovery.

CPR is a coalition of more than 50 national consumer, clinician, and membership organizations that advocate for policies to ensure access to rehabilitative care so that individuals with injuries, illnesses, disabilities, and chronic conditions may regain and/or maintain the maximum level of health and independent function. CPR is comprised of organizations that represent patients—as well as the providers who serve them—who are frequently in need of medical rehabilitation services in a variety of settings, including inpatient rehabilitation hospitals, skilled nursing facilities, outpatient clinics, physician and therapy offices, and in the home.

CPR appreciates the work that HHS, especially the Centers for Medicare and Medicaid Services (CMS), has completed thus far to protect access to health care during the COVID-19 pandemic. As the Department considers further regulatory action to extend certain flexibilities past the end of the public health emergency (PHE) declaration, we offer the following recommendations for policies specifically impacting patients in need of rehabilitation care.

Waiver of the IRF Intensity of Therapy (“Three-Hour Rule”) Requirement (#216)

Among other criteria, CMS mandates that a patient must require, and be able to participate in, at least three hours per day, five days per week (or fifteen hours over a seven-day period) of multidisciplinary “intensive” rehabilitation therapy in order to qualify for admission to an IRF. Prior to 2010, CMS regulations for IRFs explicitly recognized four “core” rehabilitation therapies as countable toward the “three-hour rule:” physical therapy, occupational therapy, speech therapy, and/or orthotics and prosthetics care, but allowed the physician and rehabilitation

team to prescribe the appropriate mix of “other therapeutic modalities” in addition to the skilled services listed in the regulation. This physician flexibility comported with the settlement and order in *Hooper v. Sullivan*, (D. Conn. 1989), which required an individual assessment of what is actually required by each patient and made clear that a hard and fast numerical rule could *only* be used to screen for coverage, not to grant or deny Medicare coverage. (Note: originally, rehabilitation nursing was considered one of the core disciplines that counted toward the three-hour rule).

In 2010, CMS revised the IRF regulations to limit the three-hour “rule” to *only* four modalities, removing the rehabilitation team’s discretion to count additional therapeutic services towards the rule. CMS and, subsequently, Congress waived the three-hour rule in its entirety during the duration of the PHE, in order to ensure that rehabilitation patients would not lose their eligibility for IRF coverage if they were not able to receive the mandated three daily hours of therapy as a result of COVID-related upheaval in the health care system.

This waiver has been an important tool allowing IRFs to provide appropriate, patient-centered care during the pandemic. Active COVID patients, as well as recovering COVID patients, are often not able to tolerate three hours of therapy per day, but many nevertheless require intensive, coordinated rehabilitation care (the basic Medicare criteria for IRF services) in order to maintain or regain function lost due to COVID infection. ***CPR urges CMS to maintain the three-hour rule waiver at least for the duration of the PHE and to extend the full waiver for at least six months after the PHE declaration is lifted.*** As enunciated in *Hooper*, this is actually what is required by the law.

CPR also reiterates that despite the typical treatment of the three-hour rule as a hard and fast criterion for IRF coverage, the Medicare program through both guidance and court action has been very clear that “rules of thumb” in general, and the three-hour rule in particular, are not permissible bases upon which to make a determination of medical necessity and coverage of care.¹ In fact, the Secretary of Health and Human Services explicitly agreed that “denials of admissions, services, and/or Medicare coverage based upon numerical utilization screens, diagnostic screens, diagnosis, specific treatment norms, *the ‘three hour rule,’* or other ‘rules of thumb’ are not appropriate.”² Nonetheless, CMS, its contractors, and Medicare-participating rehabilitation facilities continue to view the three-hour rule as a requirement. ***Thus, CPR urges CMS to clearly state that the three-hour rule is a guide, not a determinative rule, calling for IRF patients to generally be able to participate in three hours daily of multidisciplinary, coordinated therapy and care. This statement is needed to ensure that patients are able to access the care they need for their individual conditions.***

Once the waiver ends, we strongly urge that CMS modify its interpretation of the three-hour rule to expand the skilled treatments countable towards its satisfaction. The rule could maintain an explicit focus on the four “core” treatments currently identified as the basis of the patient’s plan of care upon admission. However, CMS should provide flexibility for the rehabilitation

¹ *Hooper v. Sullivan*, 1989 WL 107497 (D. Conn.).

² *Id.* (emphasis added).

physician and the IRF care team to identify additional skilled therapeutic modalities that are appropriate for the patient's needs, allowing these therapies to be counted towards the three-hour rule over the course of the patient's IRF stay. Patient needs are not static; over the course of their rehabilitation, patients are likely to benefit from different mixes of therapy, especially as they prepare for discharge to their home or, in some cases, to another setting of post-acute care.

For example, particularly when treating a post-COVID patient, IRFs may find that it is most appropriate to provide respiratory therapy to improve pulmonary function, especially if a patient has been on a ventilator. Similarly, patients who saw their overall level of function deteriorate during a long-term hospital stay for COVID-19 may need recreational therapy in addition to physical therapy in order to re-acclimate to independent life in the community.

Regardless of diagnosis, psychological and neuropsychological services are also critical in treating many patients, especially those who might be adjusting to limited function or the onset of disability. Patients should be able to participate in an intensive but tailored rehabilitation care plan, based on their specific medical and functional needs; expanding the three-hour rule will help ensure that these skilled services are available to the patients who need them. This would also provide the treating physician greater discretion to most appropriately craft a care plan to elicit the maximum level of health and independent function from the patient over the course of the IRF stay.

Regarding the financial impact of modifications to the three-hour rule, CPR notes that during the pandemic, while the full waiver of the three-hour rule has been in effect, preliminary data from IRFs across the country have shown that removal of the rule has not resulted in a notable increase in IRF admissions, nor a decrease in the amount of therapy minutes provided to patients. Simply put, IRFs are continuing to provide high levels of intensive rehabilitation care to patients in need and have not used the three-hour rule flexibility to weaken their standards of care. For this reason, we do not expect any significant fiscal impact to the Medicare program by expanding the three-hour rule; however, this expansion would lower inappropriate barriers for patients in need of relatively intense, multidisciplinary, coordinated care in IRFs.

Flexibility for IRFs Regarding the “60 Percent” Rule (#213)

In order to maintain their designation as rehabilitation hospitals, IRFs are required to follow the “60 percent rule” regarding their patient populations. At least 60 percent of the patients admitted in an IRF must meet one of 13 designated conditions, including stroke, spinal cord injury, amputation, brain injury, and other key rehabilitation conditions. During the PHE, CMS has expanded flexibility for this requirement to allow the exclusion of patients solely admitted in response to the COVID-19 pandemic. This flexibility has allowed IRFs to treat COVID patients more nimbly without jeopardizing their status as a rehabilitation hospital.

CPR encourages CMS to maintain the 60 percent rule waiver for the duration of the PHE and to extend the full waiver for at least six months after the PHE declaration is lifted.

CPR also notes that the 60 percent rule has sometimes acted as a barrier to access for patients in need of intensive rehabilitation but who do not have a primary diagnosis of one of the 13 conditions listed under the rule. The 60 percent rule puts pressure on some IRFs to turn these patients away in order to maintain their status as an IRF. However, we also recognize that the 60 percent rule is one of several distinguishing characteristics that separate IRFs from other settings of post-acute care, a distinction we feel is crucial to ensuring that the most complex patients are able to receive appropriate care to maximize their health and function.

Especially as IRFs and other post-acute care settings continue to expand their treatment of patients with long-term symptoms and secondary conditions resulting from COVID-19 infection, and as best practices evolve regarding rehabilitation for these patients, we encourage CMS to consider further reforms to the 60 percent rule if necessary to ensure these patients receive the most appropriate care in the most appropriate setting based on individual needs.

Expansion of Telehealth Services and Authorities in Medicare (Various)

Using the expanded authorities made available by Congress, CMS has greatly expanded the availability of telehealth and virtual care during the pandemic for Medicare beneficiaries. CPR notes that several of these waivers and flexibilities are limited by the authority CMS currently possesses to expand telehealth beyond the duration of the PHE, and that Congress will need to act to enable some of these flexibilities to last after the PHE is lifted. However, as the Medicare population grows accustomed to the widespread adoption of telehealth over the last nine months, we recognize that both Congress and CMS are likely to work together to consider permanent extension of some of the telehealth policies that have proliferated during the pandemic.

CPR appreciates that the rapid expansion of telehealth has allowed many Medicare beneficiaries to safely access medically necessary health care while protecting themselves from threat of infection with COVID-19. Especially for vulnerable patients with injuries, disabilities, and chronic conditions, the ability to receive medical rehabilitation services virtually has been critical for improving health and function while limiting the risk of infection by abiding by social distancing protocols. As CMS reviews the regulations governing the use of telehealth, we strongly encourage the agency to ensure that patient access to care, and patient-centered policy more generally, is the driving factor behind expansions of telehealth.

Access to telehealth has been particularly helpful for people with disabilities, even aside from the circumstances of the PHE. For example, many beneficiaries with mobility impairments have seen tremendous benefit from the ability to receive virtual evaluations and other services, given the complications associated with planning, transportation, and accessibility of in-person visits. Mobility impairments themselves limit physical access to in-person visits to health care providers. Telehealth dramatically eases the burden of mobility impairment while preserving access to care.

Similarly, many patients in need of cognitive and psychological rehabilitation services have found that virtual services may be more accessible and even potentially more effective, with the potential to cut down on distractions associated with receiving care in an unfamiliar environment. The availability of telehealth also allows patients to access care without expending

the cognitive and physical energy to transport themselves to the provider's location, which may be particularly useful for some patients. We also note that the proliferation of telehealth may allow patients to receive more stable, continuing access to therapy and other important services, with telehealth visits occurring between intermittent in-person visits in order to maintain the level of care available to the patient. We support the expansion of telehealth past the expiration of the PHE to ensure that patients are able to benefit from advances in technology that make virtual care possible.

However, it is critical that expansion of telehealth services does not come at the expense of in-person care, especially when the services needed by the patient are more effectively and efficiently provided in-person. Beneficiaries with illnesses, injuries, disabilities, and chronic conditions often need the highest levels of medical care in order to maintain, regain, and/or improve their health and function. It is crucial that beneficiaries receiving rehabilitation care are able to access the most appropriate care in the most appropriate settings. Providing telehealth options while maintaining the availability of in-person care is an important facet of person-centered care.

Permanent extension of existing waivers or new regulations expanding telehealth must ensure that telehealth is utilized only when clinically appropriate and that beneficiaries who need in-person care do not face additional barriers to access as a result of telehealth adoption. When either virtual or in-person care is considered to be equivalently appropriate for the patient's clinical needs, Medicare regulations must not promote one over the other. The decision between virtual and in-person care should be made between the patient and their provider. We encourage CMS to continue to work under the agency's current authority to ensure that patient-centered telehealth is available to as many patients as possible, in as many appropriate forms as possible, while ensuring that telehealth adds to existing forms of available care without replacing or supplanting these modalities.

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Waiver of the SNF Three-Day Prior Hospitalization Requirement (#176)

Beneficiary stays at SNFs are covered under Medicare Part A's SNF benefit for those who qualify for short-term, intensive stays and require skilled nursing and/or skilled rehabilitation care. Beneficiaries are generally eligible for payment of up to 100 days of SNF care, including room and board, skilled nursing care, durable medical equipment (DME), and other accompanying services. In order to qualify for coverage of post-acute care in a SNF, however, most Medicare beneficiaries must have a prior inpatient hospital stay of at least three consecutive days, within 30 days of admission to a SNF. This requirement has been waived during the PHE, allowing beneficiaries to qualify for temporary coverage of SNF services without a qualifying inpatient stay.

As with the other waivers discussed above, *CPR encourages CMS to maintain the waiver of the prior hospital stay requirement for the duration of the PHE and for at least a six-month grace period after the declaration expires.* However, we also encourage CMS to consider broader reforms to this requirement to ensure that patients are able to access the care they need in the most appropriate setting for their needs.

The prior hospital stay requirement has become increasingly burdensome for beneficiaries who require SNF care and has acted as a barrier to coverage for critical skilled nursing services. For beneficiaries admitted under “observation” status which is provided on an outpatient basis, hospital stays may not qualify the patient for SNF admission, even if their condition makes SNF care medically appropriate. There are no clear standards for hospitals as to when patients should be admitted under observation rather than as an inpatient, and in many cases, beneficiaries may not even be fully aware of their status when they are in the hospital. This effectively directs many beneficiaries toward discharge and home health care, even when SNF admission may result in better outcomes. Worse yet, some beneficiaries are admitted to SNFs only to have coverage for the services denied later.

Patients who are in need of intensive rehabilitation care but are unable to qualify for a SNF admission may also be directed towards institutional settings, which may be wholly inappropriate for their needs. A beneficiary who could have their needs properly addressed by a short-term, intensive course of rehabilitation in a SNF should not instead be sent to a nursing home or other long-term facility, where their condition can stagnate or even worsen to the point where a higher-cost admission (such as an IRF or long-term care hospital) may be necessary. We are concerned that outdated regulatory barriers may prevent patients from accessing care to which are entitled and which can result in better outcomes and, over the long term, lower costs for the Medicare program.

CPR strongly recommends that CMS modify the existing SNF three-day inpatient stay requirement to allow observation days to be considered for meeting the three-day rule. this change would reduce burden on patients and providers and address confusion around eligibility for SNF care. Especially when the health care system continues to be strained by the COVID-19 pandemic, it is essential that CMS remove unnecessary barriers to directing patients to the most appropriate setting for their post-acute care needs, allowing patients to most quickly and effectively protect or regain their maximum levels of health and independent function and return to their homes and the community.

Therapy Assistants Furnishing Maintenance Therapy (#150)

During the public health emergency, CMS adopted on an interim basis a policy allowing physical therapists (PTs) and occupational therapists (OTs) the discretion to delegate the performance of maintenance therapy services, as appropriate, to a PT or OT assistant (PTAs and OTAs). “Maintenance” therapy assists a patient to maintain or prevent deterioration of their functional status, as opposed to improving their functional abilities. We note that CMS made this policy permanent in the 2021 Physician Fee Schedule rule released earlier this month.

CPR generally supports this policy, and we appreciate CMS' efforts to ensure that patients have access to these essential services. However, we continue to note that beneficiaries who require maintenance therapy should still have access to PTs and OTs when necessary to ensure they are achieving optimal outcomes. Expanding the types of providers that are authorized to perform this therapy under the Medicare Part B benefit will increase providers' ability to provide medically necessary maintenance therapy to patients in need of such services.

As CPR has expressed in past regulatory comments, the coalition continues to be concerned about decreased access to rehabilitation services, especially therapy services, across Medicare payment systems. In addition to recent reductions in therapy access under the SNF and HHA payment systems for Medicare beneficiaries, we have also noted our concerns about the importance of maintenance therapy, which is covered by Medicare as affirmed under the *Jimmo v. Sebelius* class action settlement but is often at risk of being cut or eliminated entirely. We encourage CMS to continue working to ensure that beneficiaries are able to access the full spectrum of medically necessary care to which they are entitled.

We greatly appreciate your consideration of our response to this RFI. Should you have any further questions regarding this comment letter, please contact Peter Thomas or Joe Nahra, coordinators of CPR, by e-mailing Peter.Thomas@PowersLaw.com and Joseph.Nahra@PowersLaw.com or by calling 202-466-6550.

Sincerely,

The Undersigned Members of the Coalition to Preserve Rehabilitation Steering Committee

Brain Injury Association of America
Center for Medicare Advocacy
Christopher & Dana Reeve Foundation
Falling Forward Foundation
National Multiple Sclerosis Society
United Spinal Association