December 28, 2020

SUBMITTED ELECTRONICALLY VIA www.regulations.gov

The Honorable Alex Azar
Secretary
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:

On behalf of the Association of Rehabilitation Nurses (ARN) – representing approximately 4,800 rehabilitation nurses and more than 14,000 Certified Registered Rehabilitation Nurses (CRRN) that work to enhance the quality of life for those affected by physical disability and/or chronic illness – we appreciate the opportunity to comment on the Department of Health and Human Services' (HHS) Request for Information on Regulatory Relief to Support Economic Recovery.

Overview of Rehabilitation Nursing

Rehabilitation Nursing is a philosophy of care, not a work setting or a phase of treatment. We base our practice on rehabilitative and restorative principles by: (1) managing complex medical issues; (2) collaborating with other specialists; (3) providing ongoing patient/caregiver education; (4) setting goals for maximum independence; and (5) establishing plans of care to maintain optimal wellness. Rehabilitation Nurses practice in all settings, including freestanding rehabilitation facilities, hospitals, long-term subacute care facilities/skilled nursing facilities (SNFs), long-term acute care facilities, comprehensive outpatient rehabilitation facilities (CORFs), home health agencies (HHAs), and private practices.

Rehabilitation Nurses take a holistic approach to meeting patients' nursing and medical, vocational, educational, environmental, social, spiritual, and safety needs. We lead and coordinate rehabilitation, restorative care, and community reintegration for populations across all age groups and ethnicities across the care continuum, from ambulatory care to hospice. Rehabilitation nurses begin to provide care to individuals, their families, and caregivers soon after the onset of a disabling injury or chronic illness and continue to provide specialty care, patient and family education, and care transition planning that empowers these individuals to return home, work, and/or school. Rehabilitation Nurses, in collaboration with interdisciplinary

teams, provide comprehensive, population-specific care management to access health care services, adaptive technology and equipment, and community resources.

ARN supports efforts to ensure persons with disabilities and chronic illnesses have access to the appropriate level of rehabilitation services to maximize functional outcomes, independence, and quality of life. Specifically, as a part of its mission, ARN stands ready to work with policymakers at the local, state, and federal levels to advance policies and programs that promote maximum independence for all persons in need of rehabilitation.

Expansion of COVID-19 Flexibilities to Support Rehabilitation Care

ARN appreciates the efforts taken by HHS, particularly the Centers for Medicare and Medicaid Services (CMS), to provide regulatory flexibility and temporary waivers in response to the COVID-19 pandemic. ARN believes that a number of these actions have been especially beneficial to rehabilitation patients across settings of care, and we urge HHS to make these actions permanent past the expiration of the public health emergency (PHE). Below, please find a summary of ARN's recommendations regarding key waivers.

1. *Expansion of Telehealth Flexibilities (Various Actions)*

Through the expanded authorities made available by Congress, CMS has greatly expanded the availability of telehealth and virtual care during the pandemic for Medicare beneficiaries. ARN and the rehabilitation nurses we represent have seen the benefit of these flexibilities firsthand, both for rehabilitation patients and providers. Especially during the pandemic, when it is critical to promote social distancing to protect the vulnerable patients served in post-acute care settings, the wider availability of telehealth has allowed providers to serve patient needs in a variety of ways.

For example, patients who have difficulty presenting for in-person appointments, whether due to lack of transportation, disability, or increased vulnerability to COVID-19 infection, have been able to access critical therapy services virtually to maintain and regain function while at home. Patients who have been discharged from post-acute care settings, especially those who live far from the site of their care, have been better able to follow-up with their providers and receive post-discharge care. We have also seen that many rehabilitation services, including cognitive and psychological rehabilitation services, have been just as effective, and in some cases, even more effective, as in-person services, while increasing accessibility for the patients we serve. Additionally, the availability of telehealth has been critical to provide specialty care for patients diagnosed with COVID-19 and/or the long-term, secondary complications and disability due to the virus. COVID-19 positive patients may not always be able to be safely transported to a provider facility; allowing reimbursement for telehealth is essential to protecting these patients' function and independence through virtual rehabilitation care.

ARN strongly supports the continued availability of telehealth services after the expiration of the PHE declaration. Recognizing that some of the agency's expanded authorities must be granted through legislative action, we encourage CMS to continue working to increase beneficiary access to telehealth even after the COVID-19 pandemic has subsided. Of course, it is

critical that the expansion of telehealth services does not come at the expense of in-person care, especially when the services a patient needs are more effectively and efficiently provided in person. The beneficiaries that ARN members serve often require the highest levels of care in order to maintain, regain, and/or improve their health and function, while preventing complications and reducing recidivism. It is crucial that these patients continue to be able to access the most appropriate care in the most appropriate settings, whether that is in-person services in an inpatient rehabilitation facility or unit (IRF), SNF, acute-care hospital, or other setting for inpatient care; care provided in-person at home or in the community; or virtual care provided by a qualified provider.

ARN urges CMS to provide patients with access to telehealth and virtual care after the PHE when appropriate, but to ensure that telehealth does not replace, supplant, or otherwise pose a barrier to accessing in-person care.

2. *Modification of the IRF Face-to-Face Requirement (Action #119)*

During the PHE, CMS has specifically modified the requirement that rehabilitation physicians in IRFs conduct three "face-to-face" visits with individual patients per week to allow these visits to be conducted via telehealth. ARN appreciates this flexibility provided during the PHE, which allows IRF providers to more efficiently manage inpatient rehabilitation patients while protecting both patients and providers. ***ARN encourages CMS to maintain this waiver during the PHE, but to return to the face-to-face requirement for IRF patient visits once the PHE is lifted.*** This will help ensure that patients receive the individualized care that makes up part of the core of IRF care.

However, ARN does wish to note the importance of making virtual visits available in IRFs beyond the mandated face-to-face visits. Our members have noted that the expanded availability of virtual visits has been especially helpful in freestanding IRFs that might not have certain specialty providers (such as urologists, gastroenterologists, etc.) physically available onsite. Allowing IRFs to utilize virtual visits after the PHE can ensure that patients are able to access specialized expertise as needed for their individual conditions from consultants located outside of the IRF, which can reduce the burden of transporting and escorting patients to outpatient appointments and unnecessary transfers or admissions to other settings, including short-term acute care hospitals, therefore decreasing workforce burden and costs. As CMS continues to review policies for expanding telehealth availability past the end of the PHE, ***ARN encourages the agency to allow access to virtual visits in IRFs in addition to the three weekly face-to-face visits mandated by the IRF coverage criteria.***

3. *Intensity of Therapy Requirement ("Three-Hour Rule") for IRFs (Action #134)*

Among other criteria, CMS mandates that a patient must be require and be able to actively participate in at least three hours per day, five days per week (or fifteen hours over a seven-day period) of "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.

In 2010, CMS revised the IRF regulations to limit the three-hour rule to *only* the four core 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 and necessary tool to provide appropriate patient care in IRFs while combatting the various impacts of the pandemic. Active COVID-19 patients, as well as recovering COVID-19 patients, are often not able to tolerate three hours of therapy per day, but many nevertheless require intensive, coordinated rehabilitation care in order to maintain or regain function lost due to COVID-19 infection. ***ARN encourages CMS to maintain the three-hour rule waiver for the duration of the PHE.***

The three-hour rule is an important aspect of the IRF coverage requirements and helps ensure that patients receive rehabilitation care in the most appropriate setting for their individual needs. However, ***ARN has long expressed concern that the current interpretation of the three-hour rule limits the availability of a broad spectrum of rehabilitation therapies, impacting the ability of IRFs to provide the most effective, patient-centered care***.

ARN encourages CMS to expand the interpretation of the three-hour rule when considering actions extending past the end of the PHE declaration. Specifically, we encourage the agency to return to the pre-2010 regulations, which allowed for additional therapeutic modalities to count towards satisfaction of the rule based on the patient's condition and the determination of the rehabilitation physician and care team. Particularly as IRFs continue to treat patients with long-term post-COVID-19 symptoms, it is even more critical that patients in need of intensive, inpatient rehabilitation are able to access a mix of skilled rehabilitation nursing and interdisciplinary services to address their particular needs.

For example, COVID-19 patients who have been put on ventilators during the acute phase of the virus may need respiratory therapy in order to regain pulmonary function and be able to breath independently. 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. Expanding the three-hour rule to account for these and other skilled therapeutic modalities is critical to ensuring that all patients can access the most appropriate care they need. Patients should still be required to receive intensive therapy in order to qualify for an IRF, as opposed to another post-acute setting; importantly they should be able to participate in a rehabilitation care plan tailored to their unique medical and functional needs.

4. *SNF 3-Day Prior Hospitalization (Action #176)*

Prior to the PHE, individuals seeking admission to a SNF needed to meet the "three-day rule" in order to qualify for Medicare coverage of SNF extended care services. This rule requires a medically necessary inpatient hospital stay of at least three consecutive days in the prior 30 days before their 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.

While intended to ensure that only individuals truly in need of long-term, skilled rehabilitation therapy services are admitted to SNFs, the three-day rule has become a barrier for many patients to qualify for SNF admission. Especially when caretakers have tried to keep loved ones in the community, a worsening condition may warrant immediate admission to a SNF, without necessitating an inpatient hospital stay. In such situations, the three-day rule often means that either the individual is unable to receive coverage for SNF services, effectively denying care for elders unable to pay out of pocket, or the elder may seek a qualifying inpatient admission that is unnecessary or inappropriate for their individual needs. These actions can result in unnecessary costs and strains to the health care system, especially if the elder seeks admission through an emergency department visit.

ARN strongly encourages CMS to broadly re-think the prior hospitalization requirement for SNF admission past the end of the PHE declaration. In order to most appropriately serve individuals in need of post-acute care, including those who may be suffering from long-term COVID symptoms and secondary conditions, CMS should provide coverage of SNF services for Medicare beneficiaries if a considered assessment of the individual's condition by a qualified provider determines that SNF care is warranted. This change would cut down on unnecessary inpatient hospital admissions solely intended to meet the SNF qualifications and would help ensure that patients are directed to the most appropriate setting for their individual needs, rather than directed into the setting that is most convenient for the requirements of coverage. ***ARN continues to emphasize the importance of matching the right person to the right setting at the right time, based not on regulatory measures but clinical indications.***

If CMS is not willing to revise the prior hospitalization requirement entirely, ***ARN encourages a permanent expansion of the three-day rule to allow days spent in an acute care hospital under "observation" status to count towards satisfaction of the requirements for SNF coverage.*** Too often, beneficiaries are denied SNF care due to their admission status as an observation patient or have their inpatient stay arbitrarily extended to fulfill the requirement in order to qualify them for the setting in which they should be receiving care.

5. *Flexibility for IRFs Regarding the "60 Percent Rule" (Action #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.

The impacts of the COVID-19 pandemic will be far-reaching and will last much longer than the declared PHE. In order to allow IRFs to treat the right patients in the right setting for their individual needs, especially patients in need of rehabilitation for the long-term sequelae of COVID-19, ***ARN encourages CMS to consider permanent expansion of the 60 percent rule.*** As more and more rehabilitation settings treat so-called "COVID long-haulers," it is important that these patients be able to receive care in an IRF when they need intensive, inpatient rehabilitation, as many of them will.

During the PHE, many IRFs have been able to establish COVID-19 recovery programs, utilizing the flexibilities in the 60 percent rule provided by CMS. Prior to the waiver, many of these patients would not satisfy the requirements of one of the 13 core diagnoses under the rule, limiting their ability to be admitted to an IRF. However, the pandemic has demonstrated that these post-COVID-19 patients are clearly in need of, and can significantly benefit from, inpatient rehabilitation. Given the particular impacts of COVID-19 on heart and lung function, ***ARN urges CMS to add cardiac and pulmonary diagnoses to the list of qualifying diagnoses for the 60 percent rule.***

Additionally, it is becoming clear that many COVID-19 patients are suffering severe, long-term consequences for their health and function after contracting the virus, and some may even develop permanent disability stemming from COVID-19 complications. As clinicians and researchers continue to develop a more in-depth understanding of these long-term consequences, ***ARN urges CMS to add COVID-related diagnoses, including post-COVID syndrome, to the list of diagnoses for the 60 percent rule***. IRFs and other settings of post-acute care will continue to play a critical role in treating and rehabilitating patients with active COVID-19 infection as well as long-term sequelae; many of these patients will require the intensive treatment provided at IRFs in order to maintain or regain lost function due to COVID-19.

Finally, ***ARN urges CMS to consider the addition of cancer diagnoses as conditions satisfying the 60 percent rule***. Many cancer patients face significant functional loss and disability after undergoing potentially debilitating oncology treatments or surgeries, and providers have found significant benefit in offering post-oncology rehabilitation. In fact, some IRFs and other post-acute care providers have found value in setting up "pre-hab" programs for patients undergoing cancer treatments, in order to help prevent or mitigate any deterioration of function as a result of these treatments. Expanding the 60 percent rule to include cancer diagnoses would help more patients access critical post-oncology rehabilitation and prevent ensuing complications and further loss of function and life.

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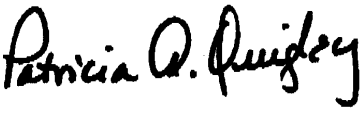
Conclusion

ARN appreciates the opportunity to provide comments to HHS regarding the regulatory flexibilities provided during the COVID-19 PHE. We are available to work with you, your colleagues, the rehabilitation community, and other stakeholders to advance policies that ensure access to quality care for Medicare beneficiaries with physical disabilities and/or chronic disease. If you have any questions, please contact me or ARN's Health Policy Associate, Jeremy Scott (Jeremy.Scott@PowersLaw.com or 202-466-6550). We thank you for your consideration of our comments.

Sincerely,



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President