AMRPA
AMERICAN MEDICAL REHABILITATION PROVIDERS ASSOCIATION

December 28, 2020

Honorable Alex M. Azar II
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, D.C. 20201

RE: Regulatory Relief to Support Economic Recovery; Request for Information (RFI)

Dear Secretary Azar:

The American Medical Rehabilitation Providers Association (AMRPA) appreciates the opportunity to submit comments in response to the *Request for Information (RFI) regarding Regulatory Relief to Support Economic Recovery* published in the Federal Register on November 25, 2020 in response to the COVID-19 public health emergency (PHE). AMRPA is the national trade association representing more than 650 freestanding inpatient rehabilitation facilities and rehabilitation units of acute-care general hospitals (IRFs).[1] The vast majority of our members are Medicare participating providers. In 2018, IRFs served 364,000 Medicare beneficiaries with more than 408,000 IRF stays.[2]

AMRPA applauds HHS and CMS for all of the COVID-19-related flexibilities[3] granted to date, as well as CMS' responsiveness to and recognition of the inpatient rehabilitation field during the PHE. As discussed more below, many actions taken by the Department and its agencies have given providers the tools and resources needed to more effectively respond to the PHE in their communities. AMRPA also recognizes that CMS has already implemented policies that reflect lessons learned during the PHE, and appreciates actions such as the permanent elimination of the Post-Admission Physician Evaluation (PAPE) requirement for IRFs in the FY 2021 IRF PPS final rule (following its temporary relaxation in the COVID-19-related March 31, 2020 interim final rule) and new telehealth expansions granted in the CY 2021 Physician Fee Schedule.

Due in part to the flexibilities granted by CMS and the distinct competencies and capabilities of IRFs, our hospitals have continued to safely and effectively treat traditional rehabilitation patients throughout the PHE, while also treating seriously afflicted and recovering COVID-19 patients in need of intensive

[1] Inpatient rehabilitation facilities (IRFs) – both freestanding and units located within acute-care hospitals – are fully licensed hospitals that must meet Medicare Hospital Conditions of Participation (COPs) and provide hospital-level care to high acuity patients. IRFs' physician-led care, competencies, equipment and infection control protocols are just some of the features that distinguish the hospital-level care provided by IRFs from most other PAC providers.
[2] MEDICARE PAYMENT ADVISORY COMM., REPORT TO THE CONGRESS, MEDICARE PAYMENT POLICY xiii-xxvi (2020).
[3] AMRPA recognizes that CMS responded to this PHE through numerous channels, including 1135 waivers, regulatory changes, and several other authorities. However, for brevity and clarity, AMRPA refers to "waivers" and "flexibilities" throughout this letter to generally mean any changes CMS made through waiver authority, regulatory changes, or other means in response to the COVID-19 PHE.

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rehabilitation and acute-care surge patients. As part of this complex response effort, IRFs have gone to significant lengths to build COVID-19-specialized units, create negative pressure rooms, convert double-occupancy into single-occupancy rooms, and redeploy staff. As more research emerges related to the long-term and profound impacts COVID-19 has on survivors,[4,5,6] the intensive, interdisciplinary rehabilitative care IRFs provide is all the more critical so that patients can overcome debilitating after-effects of the disease. It is therefore critical that HHS and CMS take steps to ensure IRFs have the resources necessary to appropriately and adequately treat patients for the duration of the PHE and beyond, and we appreciate the opportunity to respond to an RFI that seeks this exact information.

Based on extensive communication with our IRF members across the country, AMRPA offers several regulatory-focused recommendations on how to continue to best support patients and providers during and immediately after the PHE. This includes ensuring that the PHE stays in effect and its underlying flexibilities remain in place until it is clear that the health care system and associated COVID-19 metrics have stabilized across the country. Further, hospitals – including IRFs – have made unprecedented changes to operations and care protocols, and many of those changes were facilitated by these waivers. Providers therefore need and should be granted several-months' notice prior to the termination of any waiver. This will help with the transition and avoid unnecessary disruptions in care and risks to safety. Lastly, our comments touch on how flexibilities granted during the PHE require reconsideration or modernization of existing program rules. In summary, our recommendations include:

- HHS and CMS must keep the national PHE declaration in place until a robust set of criteria are met and keep *all* granted waivers and flexibilities available for the duration of the declared PHE.
- HHS and associated agencies must develop a set of standardized waivers that will automatically be in effect during any future PHE, with additional flexibilities available as needed to reflect the emergency at-hand.
- CMS should consider re-implementing some of the since-expired flexibilities (e.g., audit relief) for the duration of the declared PHE.
- CMS should use its discretionary authority to prohibit the use of prior authorization by Medicare Advantage (MA) plans for the duration of the current PHE and future PHEs.
- HHS and CMS must work with the 117th Congress to permanently implement some of the critical telehealth-related waivers and flexibilities granted during the PHE (e.g., the recognition of physical therapists, occupational therapists, respiratory therapists and speech-language pathologists as telehealth providers).
- HHS and CMS should engage with the field to determine an appropriate extension period for certain waivers (e.g., one-year after the PHE is declared over) due to the care needed by COVID-19 "long-haulers" – such as the 60% rule and 3-hour rule
- For all waivers and flexibilities, no matter their duration, HHS and associated agencies must provide timely guidance and clarification to contractors. To this end, specific guidance must be provided about how PHE-period claims will be audited as well as the documentation and

[4] Simpson, R., & Robinson, L. (2020). Rehabilitation After Critical Illness in People With COVID-19 Infection. American journal of physical medicine & rehabilitation, 99(6), 470–474. https://doi.org/10.1097/PHM.0000000000001443
[5] Carfì, A., Bernabei, R., & Landi, F. (2020). Persistent symptoms in patients after acute COVID-19. Jama, 324(6), 603-605.
[6] Goërtz, Y. M., Van Herck, M., Delbressine, J. M., Vaes, A. W., Meys, R., Machado, F. V., ... & van Loon, N. (2020). Persistent symptoms 3 months after a SARS-CoV-2 infection: the post-COVID-19 syndrome?. ERJ open research, 6(4).

reporting requirements that are in effect during that time. This will help ensure IRFs and other providers are clear in their adherence to admission rules, medical necessity criteria, and other key compliance issues that may be impacted by the waiver in effect.

These recommendations are discussed in further detail below:

I. HHS and CMS Must Maintain All Granted Waivers and Flexibilities for the Duration of the PHE

Many flexibilities provided by CMS have given IRFs and other post-acute providers with much-needed bandwidth to meet the demands of their communities during this crisis. In addition to the support that IRFs have been able to offer their communities when acute-care hospitals face surge-capacity, it has also become clear that the varying complications and sequelae of COVID-19 can often be best addressed in the rehabilitation hospital setting. This multi-faceted, complex IRF response effort has been enabled by flexibilities such as the waiver of the intensity of therapy requirements, remote physician visits and team meetings, 60 percent rule exclusions, and intermingling of acute and post-acute patients (among numerous others). AMRPA recognizes that many of these requirements purposefully reflect the specialized rehabilitation care provided in IRFs compared to other PAC settings. However, given the continued COVID-19 surge across the country and related demands facing all hospital providers, we believe all waivers that impacted IRF care and admissions must be maintained for the duration of the PHE.

Hospitals across the country, including IRFs, are on the front lines of meeting their community's need for care. Given the current upward trend of infections and hospitalizations, these hospitals expect to continue these efforts indefinitely and would be seriously impeded if they no longer had access to the waivers currently available. AMRPA applauds CMS' repeated assertion during the PHE that its overarching goal is to ensure that every patient in need of a hospital bed will be able to access one, and the waivers that collectively facilitate timely admission to IRFs are a critical part of this effort. Therefore, given the anticipated long tail of this pandemic, the ongoing fluctuations in case counts across the country, and the patient safety measures all hospitals are taking, AMRPA implores CMS and HHS to keep the national PHE declaration in place *along with* all currently available flexibilities to hospital providers. For IRFs, these key waivers include, but are not limited to:

- Waiver of the 3-hour rule (specifically 42 C.F.R. § 412.622(a)(3)(ii))
- Permitting remote rehabilitation physician visits
- Permitting remote therapy services
- Recognition of therapists as telehealth providers
- Exclusion of admissions from 60% rule calculations
- Allowing acute-care inpatients to be treated in IRF units
- Allowing IRF patients to be treated in acute-care beds
- Waiver allowing freestanding IRFs to admit acute-care "surge" patients and submit claims under the IRF PPS under certain conditions

In addition to the aforementioned waivers and flexibilities, certain regulations and requirements have been re-implemented since the early months of the PHE. Early on, CMS waived IRF QRP requirements for Q4 of 2019 and Q1 and Q2 of 2020 and delayed implementation of the IRF-PAI v.

4.0 and associated SPADEs; however, effective July 1, 2020, IRF QRP requirements are back in place. Additionally, CMS suspended medical reviews and audits but have since reinstated them. AMRPA recognizes the importance of program integrity tools such as quality reporting rules, audits and medical reviews; however, the unprecedented demands of patient care at this stage of the PHE (as well as staff shortages facing many providers) make these types of requirements untenable for many IRFs. AMRPA therefore urges CMS to reinstate the IRF QRP waiver and suspension of medical reviews and audits for the duration of the PHE.

AMRPA also asks CMS to take action with respect to MA prior authorization. While AMRPA greatly appreciated CMS' early leadership in calling on plans to waive prior authorization in March, MA plans have now generally reinstated these policies despite the continued demands facing hospitals and urgent hospital-level care needs by COVID-19 survivors and other vulnerable patients. Since prior authorization policies went back into effect, AMRPA members are once again reporting issues tied to prior authorization in discharges from acute-care hospitals and admissions to IRFs, which are tying up valuable resources that are needed to meet the needs of surges of COVID-19 and other patients throughout the country. AMRPA therefore urges CMS to use its discretion authority to require MA plans waive prior authorization practices for the duration of the PHE. AMRPA additionally believes that permanent prior authorization policy changes should be made in light of the impact of the waivers early in the pandemic that facilitate timely and effective access to IRF care, such as taking overturned denials into account in the plans' Star Rating system.

In addition, AMRPA believes the aforementioned waivers and flexibilities are commonsense measures that should be part of a standard response plan for any future PHE. The waivers and flexibilities have allowed providers to quickly and appropriately respond to urgent patient needs, and we believe providers having access to them immediately upon declaration of a PHE would be a prudent step. Therefore, AMRPA recommends HHS and CMS issue documentation that the above waivers will be available to providers for any future declared PHE, which would apply to all IRFs during a national PHE and to IRFs in an affected community in a state or regional PHE. This would be in addition to any other flexibilities that may be needed in light of the specific nature of the PHE.

AMRPA also requests that HHS ensure that waivers that are in effect during the PHE are uniformly initiated *and* terminated to avoid confusion and operational disruption. In particular, AMRPA members have raised concern about some of the waivers that apply to freestanding IRFs, which are tied to their states' stage of reopening. As HHS may be aware, many states have had to go back and forth between stages or create hybrid stages, creating significant burdens for IRFs as they determine whether or not certain flexibilities are available. AMRPA therefore supports waivers being tied to the PHE itself being in place rather than tied to any state-specific metrics, which are prone to change and may not reflect the demands facing hospitals in that state.

Finally, when HHS and CMS do consider ending the PHE, providers will need an extensive runway to facilitate their transition. As HHS and CMS appreciate, hospitals have made unprecedented changes to operations and care protocols, and many of those changes were facilitated by these waivers. Therefore, hospitals need and should be granted several-months' notice prior to the termination of any waiver. This will help with the transition and avoid unnecessary disruptions in care and risks to safety.

Recommendations:

1. **HHS and CMS must keep all current waivers and flexibilities in place for the duration of the PHE.**
2. **CMS should reinstate the suspension of medical reviews and audits, as well as the waiver of IRF QRP submission requirements for the duration of the PHE.**
3. **CMS should use its statutory authority to mandate MA plans waive prior authorization requirements for the duration of the PHE.**
4. **HHS and CMS should include the above waivers and flexibilities in any standard response to future PHEs.**
5. **HHS should eliminate the use of states' "re-opening stages" as a measure of whether certain waivers are in effect given that states have changed stages repeatedly throughout the PHE, and instead tie all waivers to the PHE itself being in effect.**
6. **HHS and CMS must ensure providers are given several months' notice before termination of the PHE and its associated waivers.**

II. Certain Waivers and Flexibilities Will Be Critical in the Period Immediately Following the End of the Declared PHE

As rehabilitation hospitals, intensive and interdisciplinary therapy services provided to high-acuity and medically complex patients are what sets IRFs apart from other PAC settings. AMRPA recognizes that several of regulations that reflect IRFs' distinct role in the health care system. However, as CMS is aware, the PHE has created a number of capacity challenges in both acute- and post-acute care settings. IRFs have continued to treat traditional rehabilitation patients, as well as recovering COVID-19 patients, acute-care patients related to surge capacity issues, and sub-acute (SNF) level patients who are unable to be discharged to a SNF. Furthermore, AMRPA believe it is likely that IRFs will see increasing numbers of COVID-19 survivors in need of inpatient rehabilitation, even after the PHE is officially declared over. As such, AMRPA believes CMS should thoughtfully consider an extended period of eligibility for certain waivers that have been utilized by IRFs during the PHE.

First, AMRPA recommends the waiver of the "60 percent rule" related to IRF admissions remain in effect for an appropriate period after the PHE is declared over. Given the long-term and evolving recovery needs of COVID-19 survivors, this flexibility is critical to ensure these patients have access to inpatient rehabilitation. In tandem with this request, AMRPA asks that CMS engage with its contractors to ensure that 60% compliance reviews are performed consistently and accurately for the period in which this waiver is in place. Further, AMRPA recommends CMS use the extended waiver period evaluate and, as necessary, modernize the 13 conditions that fall under the 60 percent rule to make sure it captures the full range of patients in need of inpatient rehabilitation. AMRPA would look forward to engaging with CMS on this important undertaking.

Second, AMRPA believes the three-hour rule waiver warrants similar consideration. Considering the range of complex patients that have received care in IRFs during the pandemic, some IRFs have found that the rigid requirements of three hours of therapy per day, five days per week are often unable to be tolerated by patients recovering from severe illness in IRFs – such as COVID-19. With the "long tail" of recovery for COVID-19 survivors, AMRPA believes that care and recovery would be disrupted if the three-hour rule went back into effect immediately after the PHE is declared over. In addition, many IRFs have already experienced staff shortages which will likely be exacerbated in the coming

months, which may create additional compliance challenges (especially if patient volume is higher than normal). AMRPA therefore recommends waiver of the "3-hour rule" remain in place for an appropriate period of time (e.g., for a one-year period following conclusion of the PHE) and that CMS utilize this extended timeframe to consider other potential modifications to the 3-hour rule regulatory requirements (e.g., the types of therapies that can count towards the 3-hour threshold).

Recommendations:

1. **CMS should waive the "60 percent rule" and 3-hour rule for an appropriate period of time after the PHE declaration ends in light of the long-term care and recovery of COVID-19 survivors.**
2. **CMS should use the extended waiver period to determine whether and how the 3-hour rule and 60% requirements should be modernized based on the changes in care delivery during the PHE.**

III. Recommendations for Permanent Implementation

Telehealth and Remote Patient Monitoring

The PHE has highlighted a number of regulatory changes that are appropriate for implementation on a permanent basis. Some of the most important waivers granted during the COVID-19 PHE relate to telehealth expansion, particularly for medical rehabilitation patients. In particular, AMRPA strongly supports CMS' decision to (1) expand the list of telehealth services that can be provided in the Medicare program via telehealth to include therapy services, (2) recognize therapists – including physical therapists, occupational therapists, and speech-language pathologists – as eligible telehealth providers, (3) relax distant site guidelines, (4) allow the use of audio-only telehealth services, and (5) allow remote patient monitoring. Many of our hospital members report that these waivers allow patients to continue the outpatient therapy component of their intensive rehabilitation program without undertaking the risk of entering the hospital or outpatient care setting.

Implementing these waivers on a permanent basis would allow beneficiaries in rural areas to have improved access to care – particularly to specialists who may be located in urban areas, address transportation challenges, and provide savings to the Medicare Trust Fund. In particular, allowing for remote patient monitoring on a permanent basis will continue to promote improved access to care for Medicare beneficiaries. Similarly, recognizing therapists as telehealth providers and allowing for the provision of therapy services via telehealth would ensure beneficiaries have access to critical therapy services and do not suffer functional losses or an increased risk of complications. AMRPA agrees with a number of points raised by the Federal Trade Commission (FTC) in its May 29, 2020 correspondence with CMS. As the FTC notes, authorizing therapists as telehealth providers on a permanent basis "could enhance the availability of therapists, access to care, choice of provider, competition, and quality, and also could reduce costs," and that "such improvements may especially benefit rural and underserved communities, as well as patients for whom travel is difficult."

While AMRPA understands that CMS is limited in its authority to permanently include telephone-only services for reimbursement, our members—particularly in rural areas—have concerns that requiring both audio and visual capabilities for the provision of telehealth will dramatically increase preexisting disparities within the Medicare population. Throughout a significant portion of the United States, broadband internet access—a necessity for audio/visual telehealth communications—continues to be

limited. Even for those who do not live in an area without broadband there are also other barriers to use of virtual technology. Many Medicare beneficiaries do not have access to a smartphone, tablet, computer, or other internet-connected camera. Further, many patients, particularly those in need of rehabilitation, have cognitive and/or linguistic deficits that may limit the practical use of virtual technology. Requiring that technology used for telehealth include both audio and visual capabilities would only serve to create additional disparities for already potentially vulnerable populations. AMRPA appreciates that CMS expanded the availability of audio-only services during the PHE. We recommend CMS extend this flexibility to as many services as possible for the duration of the PHE. Further, we ask CMS to seek the authority to include audio-only telehealth services within the telehealth regulations on a permanent basis.

Even before the COVID-19 pandemic, AMRPA is on record expressing support of efforts – such as the CONNECT for Health Act (S. 2741) – to modernize telehealth rules in the Medicare program to better reflect the state of medicine and technology. Consistent with this position, AMRPA believes that these outpatient therapy-focused waivers will prove beneficial outside of a PHE, such as when patients face other obstacles (e.g., weather, protests, or mobility restrictions) that prevent them from traveling to an IRF or outpatient therapy site. At the same time, clearer billing rules – particularly for hospital outpatient departments – may be required to ensure sufficient uptake. AMRPA recognizes that CMS is limited in its authority to permanently implement some of these waivers. We therefore urge HHS and CMS to work with Congress to ensure these flexibilities can be implemented after the PHE ends.

Virtual Team Conferences

AMRPA members greatly supported CMS' decision to allow virtual team conferences during the PHE in light of staff safety concerns. A number of multi-campus hospitals have reported that this flexibility would prove useful outside of the PHE, particularly in situations involving extreme weather, civic disruption in communities, or other issues that in which a virtual conference would provide a significant benefit to the interdisciplinary team. AMRPA members report that they were able to hold virtual team meetings that produced the same level of team engagement as in-person meetings, and AMRPA therefore believes each IRF should be able to determine if and how virtual team conferences should continue to be held following the pandemic.

Interstate Licensing Flexibilities

AMRPA appreciates the interstate licensing flexibility granted for the duration of the PHE. Numerous AMRPA members have been able to provide critical capacity to acute-care hospitals across state lines and provide both surge and COVID-19 patients with the acute beds they require. The interstate licensing flexibilities offered by CMS are being utilized broadly by IRFs and helping to ensure that patients receive the timely care they require for survival and recovery, without compromising the quality of the care they receive.

AMRPA requests that these flexibilities should be made permanent to alleviate patient access issues and address arbitrary restrictions on care options when patients live near state lines. At minimum, AMRPA recommends interstate licensing flexibilities be automatically triggered whenever a PHE is declared to ensure that partner hospitals in different states can immediately assist each other in furnishing the capacity and physician/staff access required for their patients. Additionally, and consistent with our telehealth-related recommendations, AMRPA also recommends that providers be

allowed to practice across state lines via telehealth in the same way they would be permitted to do so in-person.

Prohibition of Medicare Advantage Prior Authorization during Any Future PHE

As previously mentioned, during the early stages of the COVID-19 PHE many MA plans voluntarily waived their prior authorization/pre-authorization policies in order to ensure that patients were able to access IRF beds in the safest and most timely way possible. These voluntarily waivers enabled patients that were ready for clinical intervention to receive such care expeditiously, rather than incur the 3-5 business day delays that these policies frequently impart. Now that these prior authorization policies are back in effect, unnecessary care delays and acute-care bed utilization are occurring at the exact same time as acute-care hospitals are faced with unprecedented surges and infection control issues are being faced by many SNFs and nursing homes. The early prior authorization waivers – which were specifically encouraged by CMS – ensured patients were able to receive timely access to appropriate care in an IRF setting. The positive impact of these waivers makes it clear that all prior authorization policies must be fully and immediately suspended in all future PHEs. AMRPA also takes this opportunity to again reiterate that the use of prior authorization must be prohibited for the duration of the current COVID-19 PHE.

Recommendations:

1. **CMS should work with the 117th Congress to ensure therapists – physical therapists, occupational therapists, speech-language pathologists, and respiratory therapists – are recognized permanently as telehealth providers.**
2. **CMS should allow IRFs to continue to utilize virtual team conferences when needed in light of the needs of the IRF or IRF's community.**
3. **CMS must permanently allow the provision of therapy services via telehealth.**
4. **CMS should work with the 117th Congress to permanently relax geographic restrictions for the provision of telehealth.**
5. **CMS must seek authority to permanently allow for the provision of audio-only telehealth services.**
6. **CMS must permanently allow remote patient monitoring.**
7. **CMS must permanently eliminate state licensing restrictions.**
8. **CMS must use its statutory authority to prohibit the use of MA prior authorization in any future declared PHE.**

IV. Other Recommendations and Conclusion

AMRPA appreciates the rapid efforts taken by HHS and CMS in response to the PHE; however, we would be remiss if we did not address the role of contractors in responding to the pandemic. IRFs have concerns about the future of medical reviews and audits of Medicare claims for services provided during the PHE. We recognize that CMS has been in constant communication with providers, issued guidance and interpretations via website postings, provider calls, and several other "unofficial" means. However, AMRPA has not noted any ongoing and concurrent instructions to Medicare contractors to mirror all guidance and interpretations. Therefore, AMRPA fears Medicare contractors potentially will follow different interpretations or conclusions regarding the plethora of new rules.

AMRPA therefore strongly urges CMS to promptly collaborate with providers and to issue (or reissue) proper instructions to contractors, as well as clear guidance to IRFs regarding whether and how PHE-

period claims will be audited and the documentation and reporting requirements. This proactive step will ensure that providers, Medicare and contractors are on the same page about the waivers and flexibilities mentioned in the above sections of this letter. As we detailed in earlier sections of this comment letter, the demands facing hospitals during the PHE make unnecessary record requests or other inquiries from contractors particularly untenable. Furthermore, improving clarity on waiver compliance will avoid the burden of erroneous denials and appeals, which can lead to years-long backlogs and necessitate mass settlements and other costly resolutions.

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In sum, the work of all health care providers on the frontlines of this pandemic is far from over – and this is particularly true for IRFs and other post-acute care providers. While the current stress and demand on hospitals varies from state to state and region to region, the situation remains unpredictable and subject to sharp swings in short periods. This is clearly demonstrated by recent data reported in several states.[7] It is therefore essential that IRFs continue to have the flexibilities currently available for the foreseeable future, and at least until certain criteria are met.

AMRPA greatly appreciates the ongoing work of HHS and the waivers and flexibilities granted in response to the COVID-19 pandemic. The Association stands ready to work with CMS to help ensure IRFs are able to continue serving as critical frontline providers during the current PHE, and continue providing high-quality, intensive and interdisciplinary rehabilitation care in its aftermath. Should you wish to discuss these comments further, please contact Kate Beller, JD, AMRPA Executive Vice President for Government Relations and Policy Development (kbeller@amrpa.org / (973) 224-4501).

Sincerely,

Anthony Cuzzola
Chair, AMRPA Board of Directors
VP/Administrator, JFK Johnson Rehabilitation Institute, Hackensack Meridian Health

[7] https://www.npr.org/sections/health-shots/2020/09/01/816707182/map-tracking-the-spread-of-the-coronavirus-in-the-u-s