

April 6, 2020

SUBMITTED ELECTRONICALLY VIA www.regulations.gov

Ms. Seema Verma Administrator Centers for Medicare & Medicaid Services 7500 Security Boulevard Baltimore, MD 21244

RE: Contract Year 2021 and 2022 Policy and Technical Changes to the Medicare

Advantage Program, Medicare Prescription Drug Benefit Program,

Medicaid Program, Medicare Cost Plan Program, and Programs of AllInclusive Care for the Elderly (CMS-4190-P; RIN: 0938-AT97)

Dear Administrator Verma:

The undersigned members of the Coalition to Preserve Rehabilitation (CPR) appreciate the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed rule, Contract Year 2021 and 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly¹ (the Proposed Rule). This letter primarily addresses Medicare Advantage (MA) plans.

CPR is a coalition of 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 their maximum level of health and independent function. CPR is comprised of organizations that represent patients — as well as the clinicians who serve them — who are frequently inappropriately denied access to rehabilitative care in a variety of settings.

This response to the Proposed Rule focuses on:

• Revisions to supplemental benefits for beneficiaries with chronic conditions (SSBCI),

¹ Medicare and Medicaid Programs; Contract Year 2021 and 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly, 85 Fed. Reg. 9002 (Feb. 18, 2020). Available at https://www.federalregister.gov/documents/2020/02/18/2020-02085/medicare-and-medicaid-programs-contract-year-2021-and-2022-policy-and-technical-changes-to-the.

- Network adequacy requirements for MA plans,
- Star rating program enhancements, and
- New tools for beneficiaries under the Medicare prescription drug benefit program (Part D).

Our response also reiterates key points we addressed in previous years' comments on the draft MA and Part D Call Letter that continue to be priorities of our coalition, namely, ensuring access to care in inpatient rehabilitation hospitals and units (IRFs) under the MA program.

Supplemental Benefits for Beneficiaries with Chronic Conditions

CPR appreciates CMS' attention to implementing non-primarily health related "special supplemental benefits for the chronically ill" under the Bipartisan Budget Act of 2018. Access to a broad range of non-primarily health related items and services, such as transportation for non-medical needs and home-delivered meals, is important for enabling MA enrollees to live as independently as possible and for as long as possible in their homes and communities. Given the essential role that these items and services play in the lives of individuals with chronic conditions, we wish to reiterate our position that these benefits should also be covered for traditional Medicare beneficiaries. Making such benefits available to MA plan enrollees, but not traditional Medicare beneficiaries, exacerbates an already inequitable system where there is not a level playing field between the MA program and traditional Medicare. True choice between MA and traditional Medicare requires that benefits between these two parts of the Medicare program are comparable.

These non-primarily health related supplemental benefits should be reasonably available to all beneficiaries who meet the definition of a "chronically ill enrollee." CPR opposes any contemplated arbitrary limits on these supplemental benefits, such as dollar amounts or other limits. Such limits would restrict access to these items and services in direct contravention of congressional intent. Meanwhile, CPR supports CMS' proposal to codify the ability of an MA plan to consider social determinants, such as financial need including food and housing insecurity, in determining non-primarily health related supplemental benefits for MA plan enrollees with chronic conditions, provided that such benefits must always be available in a nondiscriminatory manner.

We appreciate that CMS proposes to adopt a uniform definition for determining which chronic conditions meet the statutory standard and support the formation of a panel of clinical advisors to establish and update this list. Such a definition is important to ensure that benefits are provided consistently and reliably across MA plans. In our comments on the 2020 Draft Call Letter, we expressed our concern that, given additional flexibility to determine which chronic conditions meet the statutory standard, MA plans could inappropriately limit access to these benefits. We urge CMS to clarify that any "flexibility to continue to innovate" provided to plans only allows MA plans to address additional conditions or needs in their population that are not on the CMS-approved list, and not to determine that CMS-identified conditions do not meet a given plan's internal criteria.

MA and Cost Plan Network Adequacy

In this rule, CMS is proposing to codify the standards and methodology used to evaluate network adequacy for MA plans. The adequacy of a plan's provider network can impact the level of access to benefits for enrollees. For MA enrollees to benefit from appropriate rehabilitation, CPR believes that MA plans must adhere to patient-friendly network adequacy standards that provide ample access to the full complement of rehabilitation and habilitation service and device providers, professionals, and facilities that provide both primary and specialty care. These services should be provided based on the individual's needs, prescribed in consultation with an appropriately credentialed clinician, and based on the assessment of an interdisciplinary rehabilitation team and resulting plan of care.

CMS is proposing to codify the list of provider and facility specialty types subject to network adequacy reviews. The facility specialty types proposed to be included do not include post-acute rehabilitation programs such as inpatient rehabilitation hospitals and units (IRFs). CPR urges CMS to include IRFs in the facility specialty types as part its network adequacy reviews. A wide range of rehabilitation provider types will help ensure that enrollees have access to the appropriate intensity and scope of needed rehabilitation services. For instance, too often enrollees across the country are diverted into nursing homes rather than IRFs because their health plans do not contract with a sufficient number of these providers. Too often, enrollees with brain injuries, spinal cord injuries, those who have sustained strokes, and others with a variety of complex but common conditions do not receive the intensive longer-term services they need because health plans do not contract with specialized brain treatment programs.

CMS is also proposing to set maximum time and distance standards for the providers and facility specialty types subject to network adequacy standards. Network adequacy standards should ensure that persons with disabilities are not burdened by significant traveling distances in order to receive covered services under the plan and recognize that many people with disabilities lack transportation options.

Additionally, CMS is proposing to credit MA organizations 10% points towards the percentage of beneficiaries residing within time and distance standards for contracting with telehealth providers for certain specialties. CPR supports increased access to care through the use of telehealth, as long as it does not come at the expense of providing quality care to people with disabilities.

People with disabilities should have access to disability-specific specialists and services, in settings that are physically accessible, and with a choice of providers—primary, specialty, and subspecialty. CPR believes that the adequacy of a plan's provider network dictates the level of access to benefits otherwise covered under the health plan. If a plan covers a benefit but limits the number of providers or specialists under that plan, coverage will be curtailed through a lack of access to providers with sufficient expertise to treat the patient. Additionally, network adequacy standards should ensure that persons with disabilities are not burdened by significant traveling distances in order to receive covered services under a plan. In light of these concerns, CMS must ensure robust network adequacy standards and these standards must be strongly

enforced. It is essential that Americans have access to affordable and meaningful coverage of rehabilitative services and devices.

Beneficiary Real Time Benefit Tool

The Proposed Rule proposes to require Medicare Part D plan sponsors to implement a beneficiary-facing "Real Time Benefit Tool" (RTBT) that would "allow enrollees to view accurate, timely, and clinically appropriate" real-time formulary and benefit information. CMS proposes to require inclusion of cost-sharing information, formulary alternatives, and utilization management requirements within the information displayed in the RTBT. We support efforts to present beneficiaries with digestible, accurate information regarding their expected out-of-pocket costs, and encourage CMS to work with plan sponsors to develop tools that present this information in plain language so that beneficiaries can make informed decisions regarding their prescriptions.

Star Rating Enhancements

The Proposed Rule includes updates to the methodology and measures for the quality rating system for MA and Part D plans ("Star Ratings program"). We appreciate CMS' proposal to increase the weight of patient experience/complaints and access measures, as these reflect key considerations for beneficiaries when evaluating and choosing a plan under these programs. The existing measures within these categories include important metrics such as ease of getting needed care, members' ratings of quality of care, and more. We are also pleased that CMS will continue to measure plans on their responses to appeals, including whether MA plans make timely decisions about appeals (measure DMC16).

We encourage CMS to consider an additional measure for MA plans that would track what percentage of denied claims are elevated to review by an independent entity. The Reconsideration to an Independent Review Entity (IRE) stage is a critical step in ensuring that beneficiaries who have had claims denied are able to have a third-party, objective review of their appeal. When evaluating plans, beneficiaries should be able to understand if a given plan issues a large number of denials at redetermination that may indicate barriers to accessing care.

CPR appreciates CMS' attention to measures relevant to individuals with disabilities and chronic conditions through the past addition of measures examining care transitions from an inpatient setting to the home, as well as the proposed measure regarding follow-up care provided after an emergency department visit for patients with multiple chronic conditions. In future iterations of the Star Ratings system, CPR recommends that CMS add measures that examine access to rehabilitation in inpatient settings (IRFs), as well as outpatient or home-based settings. We also encourage CMS to adopt measures to assess MA plan compliance with the *Jimmo v. Sebelius* settlement, which explicitly rejects an "improvement standard" and clarifies coverage for skilled services provided to Medicare beneficiaries that improve, maintain, and prevent deterioration of function in skilled nursing facilities, home health agencies, and outpatient clinics.

Such measures should focus on both access to care and the functional outcomes of rehabilitation care in these post-acute care settings. The addition of such measures would be a key tool for

determining the degree of access to rehabilitation care afforded to MA plan beneficiaries and holding MA plans accountable for ensuring access to these essential services.

Improper Use of Non-Medicare Guidelines by Medicare Advantage Plans

As reflected in CPR's comments on the CY 2020 Draft Call Letter, we reiterate our request that CMS instruct MA plans to apply CMS' coverage regulations governing IRFs under the traditional Medicare program. There are significant barriers under MA plans to patients accessing the post-acute, rehabilitative care they need. In our experience, many MA plans do not use Medicare IRF coverage criteria when determining coverage for IRF care. Instead, these plans apply private, proprietary decision support tools, including Milliman and InterQual guidelines ("non-Medicare guidelines"), to make their decisions as to which rehabilitation setting is covered for each patient. This tends to divert Medicare beneficiaries to less intensive rehabilitation settings than they are entitled to under the Medicare program, potentially risking the health and functional potential of Medicare MA beneficiaries.

In this way, patients are often denied access to clinically appropriate inpatient hospital rehabilitation services and are inappropriately diverted to less intensive levels of rehabilitative care and medical management. CMS should instruct MA plans to cease using Milliman and InterQual guidelines to determine IRF coverage and, instead, rely on the same coverage requirements applicable to Medicare beneficiaries under the traditional Medicare program. Failing to ensure a level playing field between the MA program and traditional Medicare creates an inequitable system and places burdensome restraints on beneficiaries' ability to choose the plan that is right for them.

When Medicare beneficiaries are injured, become seriously ill, or require surgery, they often require rehabilitation to regain functional losses. The acute hospital care is often just the first step toward recovery and returning to a normal life. Patients frequently require a course of post-acute, hospital-based rehabilitation that is intensive, coordinated, and provided by a multidisciplinary team led by a rehabilitation physician. Other settings of rehabilitation care are available for patients who do not require a hospital level of care, such as skilled nursing facilities, outpatient therapy programs, home care, and other settings.

For example, a patient who sustains a stroke may be left with permanent neurological damage and a need to overcome or adapt to physical or cognitive impairments. An amputee must heal from a traumatic injury while being fitted and learning to ambulate with a prosthetic limb. A patient confined to a hospital bed for a significant period of time during a serious illness will lose muscle mass and may have difficulty walking or performing basic self-care tasks. IRFs strive to improve the functional capacity and quality of life of patients recovering from surgical procedures, strokes, spinal cord injuries, brain injuries, amputations, hip fractures, and many other conditions that decrease a person's ability to function, live independently, and perform common daily activities, such as walking, using a wheelchair, bathing, or eating.

CMS has developed detailed coverage regulations for Medicare IRF coverage.² The same coverage rules apply to both traditional Medicare Part A and Part C Medicare Advantage beneficiaries. Medicare regulations are clear that Part C plans must provide all Medicare-covered services.³ These covered services include "all services that are covered by Part A," which are "basic benefits" available to Part C enrollees.⁴ Part C plans must comply with all Medicare coverage regulations and manuals.⁵

Medicare manuals are equally plain. The Medicare Managed Care Manual ("MMCM") states that a Part C "plan must provide enrollees in that plan with all Original Medicare-covered services." The MMCM instructs that "[i]f the item or service is covered by Original Medicare under Part A or Part B, including Part B prescription drugs, then it must be offered." Therefore, Part C plans must determine IRF coverage using the Part A regulations at 42 C.F.R. § 412.622 and the Medicare Benefits and Policy Manual chapter 1.

The Milliman Care Guidelines (MCG) are a proprietary decision support tool that includes inpatient admission guidelines. InterQual is also proprietary and includes clinical care guidelines. InterQual includes criteria for assessing the level of care, including acute rehabilitation. CMS has not adopted either set of guidelines, and they are not referenced in any Medicare IRF regulations or manuals. Indeed, CMS has repeatedly declined to adopt Milliman, InterQual, or any guidelines other than its own coverage criteria.

In a 2001 Federal Register preamble, a commenter criticized a CMS coverage regulation as *inconsistent* with InterQual, and CMS declined to defer to InterQual. In 2004, CMS expressly refused to adopt InterQual criteria for IRF coverage, stating that the criteria "are proprietary." In 2007, CMS described InterQual criteria as mere "guidelines." In 2010, a commenter requested that CMS remove certain procedures from the "inpatient only list" because Milliman Care Guidelines designated the procedures safe in an outpatient setting, but CMS refused, stating "we

² See 42 C.F.R. § 412.622(a). Among other requirements, to be covered in an IRF, the patient must need an interdisciplinary approach to care, be stable enough at admission to participate in intensive rehabilitation, and there must be a "reasonable expectation" that the patient will need multidisciplinary therapy, intensive rehabilitation, and supervision by a rehabilitation physician. The requirement for multidisciplinary therapy must include physical or occupational therapy. Intensive rehabilitation is defined as three hours per day, five days per week (or 15 hours per week). The therapy must be reasonably likely to result in measurable, practical improvement to the patient's functional capacity or adaptation to impairments. The rehabilitation physician must see the patient at least three times per week. Medicare coverage may not be denied based on treatment norms or rote "rules of thumb."

³ 42 C.F.R. § 422.101.

⁴ Id. § 422.101(a).

⁵ *Id.* § 422.101(b).

⁶ MMCM, ch. 4 § 10.2. This manual provision describes four exceptions, which are not applicable here.

⁷ MMCM, ch. 4 § 10.3.

⁸ 66 Fed. Reg. 59,880 (Nov. 20, 2001).

⁹ 69 Fed. Reg. 23,576 (May 7, 2004).

¹⁰ 72 Fed. Reg. 4,885 (Feb. 1, 2007).

remain convinced that these procedures could be safely performed only in the inpatient setting."¹¹

Despite this consistent and very clear guidance from CMS, rehabilitation hospitals and units, as well as physicians who practice in these settings, report that a number of Medicare Part C plans routinely deny IRF coverage based on Milliman or InterQual guidelines without applying traditional Medicare IRF coverage rules. Anecdotal evidence suggests this problem is growing in severity in the recent past. Our beneficiary and clinical member organizations inform us that a growing number of Medicare managed care cases are being diverted from an IRF level of care based on guidelines that have not been sanctioned or adopted by the Medicare program (e.g., Milliman, InterQual). This is why it is unsurprising that MedPAC's March 2017 report¹² found that MA enrollees were admitted to IRFs at approximately one-third the rate of traditional Medicare beneficiaries in 2015.

The undersigned members of CPR are concerned that some MA plans may be overriding the clinical judgment of treating physicians and the rehabilitation team, and seem to be ignoring Medicare coverage regulations. MA plans must approve IRF admissions if there is a "reasonable expectation" that the patient will need multidisciplinary therapy, intensive rehabilitation, and supervision by a rehabilitation physician." MA plans may not use proprietary decision support algorithms to deny IRF – or any other – coverage to Medicare beneficiaries with no regard to binding Medicare regulations. Such algorithms are impermissible "rules of thumb" that may not be used to deny IRF coverage. ¹⁴

The use of non-Medicare guidelines by some MA plans jeopardizes the health of Medicare beneficiaries. Beneficiaries are put in the position of contesting the MA plan's coverage denial, potentially delaying the needed rehabilitation to which they are entitled. Many beneficiaries are not aware that they can contest the MA plan's initial determination to deny IRF care, and they may lack the family support necessary to appeal.

The most vulnerable beneficiaries are at risk of being denied access to rehabilitation services that meet their medical and functional needs without even knowing that these decisions are being made behind the scenes, based on non-Medicare guidelines, even when they would otherwise qualify for coverage under Medicare coverage rules. Particularly given the steady growth in managed care, with the MA program now covering more than one-third of all Medicare beneficiaries ¹⁵, it is crucial that the MA program be administered in a way that protects the rights of beneficiaries and guarantees access to medically necessary care.

We therefore urge CMS to revise future Medicare rulemaking to include explicit instructions to MA plans to cease using Milliman, InterQual, or similar guidelines to determine coverage of

¹¹ 75 Fed. Reg. 71,800, 71,966 (Nov. 24, 2010).

¹² Medicare Payment Advisory Commission, Report to the Congress: Medicare Payment Policy, 298 (March 2017). [finding that 2015 Medicare admissions to IRFs were 10.3 for every 1,000 traditional Medicare patients compared to 3.7 for every 1,000 MA patients].

¹³ 42 C.F.R. § 412.622(a)(3), (a)(5).

¹⁴ See MBPM, ch. 1, § 110.2.2; Hooper v. Sullivan, No. H-80-99 (PCD), 1989 WL 107497 (D. Conn. July 20, 1989).

¹⁵ Medicare Payment Advisory Commission, Report to the Congress: Medicare Payment Policy, 365 (March 2020).

inpatient hospital rehabilitation and, instead, rely on the same coverage requirements applicable to Medicare beneficiaries under the traditional Medicare program.

We greatly appreciate your consideration of our comments on this proposed rule. Should you have further questions regarding this information, please contact Peter Thomas or Joe Nahra, coordinators for CPR, by e-mailing Peter.Thomas@PowersLaw.com or Joseph.Nahra@PowersLaw.com, or calling 202-466-6550.

Sincerely,

The Undersigned Members of the Coalition to Preserve Rehabilitation

ACCSES

American Association of People with Disabilities

American Association of Health and Disability

American Congress of Rehabilitation Medicine

American Medical Rehabilitation Providers Association

American Occupational Therapy Association

American Physical Therapy Association

American Spinal Injury Association

American Therapeutic Recreation Association

Association of Rehabilitation Nurses

Association of University Centers on Disabilities

Brain Injury Association of America

Center for Medicare Advocacy

Christopher and Dana Reeve Foundation

Clinician Task Force

Falling Forward Foundation

Lakeshore Foundation

National Association for the Advancement of Orthotics & Prosthetics

National Association of State Head Injury Administrators

National Council on Independent Living

National Multiple Sclerosis Society

Rehabilitation Engineering and Assistive Technology Society of North America

Spina Bifida Association of America

Uniform Data System for Medical Rehabilitation

United Cerebral Palsy

United Spinal Association