



September 6, 2022

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

RE: CMS-1770-P; Medicare and Medicaid Programs; CY 2023 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicare and Medicaid Provider Enrollment Policies, Including for Skilled Nursing Facilities; Conditions of Payment for Suppliers of Durable Medicaid Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS); and Implementing Requirements for Manufacturers of Certain Single-dose Container or Single-use Package Drugs to Provide Refunds with Respect to Discarded Amounts.

Submitted electronically via regulations.gov

Dear Administrator Brooks-LaSure,

The National Rural Health Association (NRHA) is pleased to offer comments on the Centers for Medicare and Medicaid Services (CMS) proposed rule for the Physician Fee Schedule proposed rule for (CY) 2023. We appreciate CMS' continued commitment to the needs of the more than 60 million Americans that reside in rural areas, and we look forward to our continued collaboration to improve health care access throughout rural America.

NRHA is a non-profit membership organization with more than 21,000 members nationwide that provides leadership on rural health issues. Our membership includes nearly every component of rural America's health care, including rural community hospitals, critical access hospitals, long-term care providers, doctors, nurses, and patients. We work to improve rural America's health needs through government advocacy, communications, education, and research.

Conversion Factor

NRHA is concerned with the net decrease in the conversion factor compared to CY 2022, particularly given the inflationary environment and supply chain challenges that rural hospitals and health care providers are facing. NRHA urges CMS to explore its authority to increase the PFS conversion factor to ensure that rural practitioners are reimbursed a rate that reflects the current economic reality.

II.D.1. Payment for Medicare Telehealth Services Under Section 1834(m) of the Act

NRHA thanks CMS for implementing provisions of the Consolidated Appropriations Act, 2022 to continue providing access to critical telehealth services for rural communities. NRHA believes that there is more to be done for rural patients that rely upon telehealth and requests CMS use its authority to continue reimbursement for certain needed telehealth services that would benefit rural.

b. Requests To Add Services to the Medicare Telehealth Services List for CY 2023

(2) Telephone E/M Services

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Audio-only telehealth should be maintained after the 151 days post-PHE period for certain services. NRHA disagrees with CMS' reading of Section 1834(m)(2)(A) and believes that it is an unduly narrow interpretation.¹ CMS interprets the provision to require that "telehealth services be so analogous to in-person care such that the telehealth service is essentially a substitute for a face-to-face encounter."² This is an unnecessarily restrictive reading of the statute. The statute only provides that reimbursement for telehealth must be equal to the amount the provider would have been paid if the service were furnished in-person. The statute is silent on whether the services must be "so analogous" to in-person care so that it is "essentially a substitute" for an in-person visit.

NRHA urges CMS to adopt a broader reading of § 1834(m)(2)(A) such that audio-only services are retained beyond 151 days post-PHE. NRHA suggests that CMS allow audio-only for telehealth visits for circumstances in which a beneficiary does not consent to audio/video technology or is not capable due to broadband or other connectivity resource issues. NRHA acknowledges that audio-only services are not appropriate for all visits and that audio/video or in-person may be better suited depending upon the nature of the visit. However, some evaluation and management (E/M) visits may be similarly as effective using audio-only as using audio/video or face-to-face encounters. Per physician discretion, audio-only visits may serve as an appropriate substitute for audio/video technology or in-person care.

Further, rural patients face unique challenges in accessing both in-person and audio/video services, creating inequities in care. Rural patients, on average, travel further to access health care than their non-rural counterparts. This disincentivizes rural residents from seeking care if they do not have the ability or resources for travel. Rural residents have benefited greatly from expanded telehealth during the PHE and consequently will suffer when the flexibilities are removed. Additionally, broadband infrastructure is lacking in rural areas and some rural residents are not capable of audio/video technology. For E/M visits, under CMS' proposal, these individuals would be forced to travel for an in-person visit because their internet does not support audio/video technology. Rural patients must not be forced to travel longer distances to care because they do not have the same access to broadband infrastructure as urban and suburban areas.

There is precedent for CMS proposing to retain an audio-only option for other types of visits. CMS proposes that audio-only will be permanently available for initiating opioid use disorder treatment with buprenorphine where patients are not capable of or do not consent to audio/video communication. In the proposed Outpatient Prospective Payment System rule, CMS is similarly proposing to allow audio-only for outpatient mental health services for patients that do not have the

¹ "The Secretary shall pay to a physician or practitioner located at a distant site that furnishes a telehealth service to an eligible telehealth individual an amount equal to the amount that such physician or practitioner would have been paid under this title had such service been furnished without the use of a telecommunications system."

² Medicare and Medicaid Programs; CY 2023 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies. 87 Fed. Reg. 45891 (July 29, 2022) (to be codified at 42 C.F.R. pts. 405, 410, 411, 414, 415, 423, 424, 425, and 455).

capability or consent to audio/video.³ While recognizing the differences between E/M visits and mental health visits, NRHA maintains that rural patients must retain access to audio-only visits where they are not capable of or do not consent to video communication. These two qualifiers for rural beneficiaries will ensure that audio-only is used only when necessary for visits that do not give rise to the need for face-to-face communication, whether in-person or through video, communication.

II.E.4. Valuation of Specific Codes for CY 2023

(34) Proposed Revisions to the “Incident to” Physicians’ Services Regulation for Behavioral Health Services

NRHA commends CMS for working within its authority to ensure that licensed professional counselors and licensed marriage and family therapists can practice with less restrictions under general supervision. By making greater use of these practitioners, rural beneficiaries will have improved access to needed behavioral health services.

(35) New Coding and Payment for General Behavioral Health Integration (BHI) Billed by Clinical Psychologists (CPs) and Clinical Social Workers (CSWs)

NRHA supports the decision to create a new G-code for behavioral health integration billed by CPs and CSWs. This will allow flexibility in workflows such that rural beneficiaries will receive needed behavioral health care and practitioners in a care team will be used most effectively.

(36) Request for Information: Medicare Part B Payment for Services Involving Community Health Workers

NRHA thanks CMS for exploring possibilities for Medicare Part B payment for community health worker (CHW) services. The field of CHWs has grown significantly in recent years and they are valuable community members that provide a range of health care services, especially in the care coordination and social determinants of health (SDOH) space. A key aspect of CHWs is their “unusually close understanding of the community served”⁴ which makes them valuable to rural communities as they understand the unique characteristics and challenges facing rural residents.

Please find our full response to the Request for Information attached to the end of our comment.

(38) Request for Information: Medicare Potentially Underutilized Services

CMS is seeking comment on how best to identify high value, underutilized health services. CMS defines high value health services as those services that provide the best possible health outcomes at the lowest possible cost.

³ Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs. 87 Fed. Reg. 44679 (July 26, 2022) (to be codified at 42 C.F.R. pts. 405, 410, 411, 412, 413, 416, 419, and 424).

⁴ Theresa H. Mason, et al., *Statewide Training Approaches for Community Health Workers*, NATIONAL ASSOCIATION OF COMMUNITY HEALTH WORKERS, 1 (Aug. 2021) <https://nachw.org/wp-content/uploads/2021/09/8.25.21StatewideTraining.pdf>.

NRHA asks that CMS consider the full continuum of obesity treatment as high value health services. Obesity as a risk factor is by far the greatest contributor to the burden of chronic diseases in the U.S., accounting for 47.1% of the total cost of chronic diseases nationwide.⁵ Rural populations experience obesity at higher rates than urban populations and this disparity appears to be growing. One study estimates that almost 39% of men and 47% of women living in rural areas are obese compared to 32% and 38% of men and women in metropolitan areas.⁶

CMS should consider the full suite of obesity treatments as high value health services because investments in obesity prevention and management could yield overall savings for the Federal government and health care systems. Total obesity-related government expenditures, including Medicaid and Medicare spending and federal outlays, are estimated to be \$91.6 billion per year.⁷ Intensive behavioral therapy is one component of obesity treatment that should be classified as high value for its potential to lower long-term health care costs. Any preventive services related to obesity, such as screenings, should also fall under high value services.

Another option for obesity treatment is Food and Drug Administration approved anti-obesity medications (AOM). Unfortunately, Medicare is the sole outlier in Federal health insurance plans as it does not cover AOM under Part D. The Veterans Health Administration, Tri-Care, the Federal Employee Health Benefit Plans, and Medicaid in 17 states cover AOM. Further, Medicare covers other obesity treatments, like behavioral therapy and bariatric surgery. Lack of access to the full scope of obesity treatments under Medicare is a health equity issue for rural beneficiaries considering the higher prevalence of obesity in rural communities. NRHA urges CMS to consider Part D coverage for AOM to ensure that Medicare beneficiaries have access to all needed obesity treatments, including AOM under Medicare Part D.

(41) Comment Solicitation on Payment for Behavioral Health Services under the PFS

NRHA appreciates CMS' review of payment methodologies for behavioral health, particularly because the services most impacted by CMS' methodology are critical for rural patients. There is precedent for CMS using flexibility to alter other payment methodologies within its authority. For example, in this rule, CMS proposes to change the methodology for methadone pricing and the payment rate for individual counseling for opioid use disorder as part of the bundled rate. We ask CMS to delve into similar possibilities for adjusting the payment methodology for behavioral health services to meet the unique needs of rural beneficiaries and the rural patient and provider mix. NRHA would be happy to partner with CMS to examine and develop proposals surrounding behavioral health payment to further access for rural beneficiaries.

⁵ Hugh Waters & Marlon Graf, *America's Obesity Crisis: The Health and Economic Costs of Excess Weight*, MILKEN INSTITUTE, 16 (Oct. 2018) https://milkeninstitute.org/sites/default/files/reports-pdf/Mi-Americas-Obesity-Crisis-WEB_2.pdf.

⁶ Craig M. Hales, et al., *Differences in Obesity Prevalence by Demographic Characteristics and Urbanization Level Among Adults in the United States, 2013-2016*, 319 JAMA 2419, 2422-55 (June 2018) <https://jamanetwork.com/journals/jama/fullarticle/2685156>.

⁷ Mina Kabiri, et al., *The Societal Value of Broader Access to Antiobesity Medications*, 28 OBESITY 429, 430 (Feb. 2020) <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7003734/pdf/OBY-28-429.pdf>.

Existing payment and time-limited grants, though important and needed, remain incommensurate with the scale of the behavioral health crisis. CMS should act boldly across permanent programs to respond to behavioral health needs of rural beneficiaries. Over the medium- to long-term, CMS and the Department of Health and Human Services should use its various demonstration authorities to develop and test alternate payment models that adequately support integrated advanced primary care inclusive of services addressing both physical and behavioral health care needs for rural communities.

Also, Medicare sets payment rates based on complexity and the relative resources needed to perform particular services, which disadvantages nonprocedural services including many behavioral health services.⁸ The Medicare Payment Advisory Commission has reported that the relative values of certain procedures may be overstated due to technological innovations and the increasing role of nonphysician practitioners (NPP),⁹ while many nonprocedural services are underpaid as they are increasingly difficult and labor intensive. Insofar as Medicare reimburses physicians three to five times more for common procedural care than nonprocedural care, Medicare is creating and reinforcing disincentives for physicians and other professionals to enter the behavioral health field and for current behavioral health professionals to accept Medicare and all other insurance that base payment on the PFS.¹⁰

We believe that the RVU rate setting system must be reevaluated and that CMS must set payment amounts that adequately reflect the value of nonprocedural services, like substance use disorder treatment and mental health care. NRHA suggests that CMS increase the average rates for primary care and other nonprocedural services by 20% relative to certain rates for specialty care on a budget-neutral basis.¹¹

II.F. Evaluation and Management (E/M) Visits

14. Split or Shared Services

NRHA appreciates that CMS has delayed until January 1, 2024, the implementation of its split services, or “substantive portion” policy finalized in the CY 2022 final rule.¹² However, NRHA is troubled by the definition of “substantive portion” that CMS adopted. We do not believe that “over half” is an appropriate definition of “substantive portion” for the purpose of paying for split services. This policy is particularly troublesome for rural communities as NPPs often provide the majority of care for rural patients and consequently will receive less payment under PFS for split or shared visits.

⁸ Maura Calsyn and Madeline Twomey, *Rethinking the RUC: Reforming How Medicare Pays for Doctors’ Services*, CENTER FOR AMERICAN PROGRESS (Jul. 13, 2018)

<https://www.americanprogress.org/article/rethinking-the-ruc/>.

⁹ MEDICARE PAYMENT ADVISORY COMMISSION, *Analysis of Disparities in Physician Compensation* (January 2019), 3

https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/contractor-reports/jan19_medpac_disparities_physiciancompensationreport_cvr_contractor_sec.pdf.

¹⁰ Christine A. Sinsky & David C. Dugdale, *Medicare Payment for Cognitive vs. Procedural Care: Minding the Gap*, 173 JAMA INTERNAL MEDICINE 1733, 1736 (Aug. 2013)

¹¹ Calsyn & Twomey, *supra* note 8.

¹² Medicare Program; CY 2022 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies. 86 Fed. Reg. 64996, 65152-53 (Nov. 19, 2021) (codified at 42 C.F.R. pts. 403, 405, 410, 411, 414, 415, 423, 424, and 425).

NPPs play an incredibly important role in the rural health care system as rural communities face physician shortages and enduring recruitment and retainment challenges. The supply of NPPs is also projected to grow by double over the next fifteen years, signaling that an increasing number of NPPs will be providing patient care.¹³ Rural practitioners will feel the brunt of the split or shared visit policy as NPPs are more likely to provide most of the care in rural areas. This creates a paradox wherein rural facilities rely upon NPPs to provide care but also need Medicare payments the most; however, under this policy rural facilities would receive 15% less because NPPs would more often provide the “substantive portion” of a visit. Rural facilities cannot take on a lesser payment amount for these services when they are already operating under razor thin margins. We are also seriously concerned about facilities and physicians making changes to workflows that would take work away from NPPs in order to retain the extra 15% reimbursement.

NRHA urges a change to the “substantive portion” definition or carve out for rural providers. Requiring that NPPs or physicians bill for the service if they provide just over half of the care is inconsistent with the plain meaning of a “substantive portion.” First, NRHA suggests that CMS reconsider relying upon time for defining “substantive portion” and revert to a narrower definition. For example, CMS should amend the definition so that the practitioner that is involved in medical decision making (MDM) may bill for the split or shared service. Alternatively, CMS could retain its current proposal but include a rural carve out or carve out for Health Professional Shortage Areas (HPSAs) and use the MDM billing policy for split or shared services in those areas only. Areas with health professional shortages are more likely to use NPPs to the extent possible under state scope of practice laws and would effectively be penalized financially under the current proposal. Additionally, CMS now has a year of data to draw upon to inform its split or shared services policy. CMS should consider looking to the data to see the accurate breakdown between physician and NPP services in split or shared visits to reframe the “substantive portion” definition.

III.L. Proposal and Request for Information on Medicare Parts A and B Payment for Dental Services

CMS notes that seniors often lack access to oral health care and therefore are at the highest risk for poor oral health. This inequity is even more acute in rural areas where dental care is lacking for all age demographics. In 2018, just over half of rural residents indicated that they visited a dentist in the past year, whereas 67% of residents in metropolitan areas had.¹⁴ Additionally, seniors in rural areas were less likely to have visited the dentist than their urban and suburban counterparts.¹⁵ Travel, affordability, and lack of dental insurance may disincentivize rural residents, especially seniors, from seeking dental care. But dental workforce shortages in rural communities also contribute to

¹³ American Association of Medical Colleges, *The Complexities of Physician Supply and Demand: Projections From 2019 to 2034* (June 2021), 47 <https://www.aamc.org/media/54681/download?attachment>.

¹⁴ Rural Health Information Hub, *Oral Health in Rural Communities*, <https://www.ruralhealthinfo.org/topics/oral-health>.

¹⁵ America’s Health Rankings, United Health Foundation, *Senior Report 2018*, (May 2018), 44 <https://assets.americashealthrankings.org/app/uploads/ahrseior18-finalv1.pdf>.

accessibility given that 67% of dental HPSAs are in rural areas.¹⁶ Almost 4,000 dental practitioners are needed in rural areas to remove these designations.¹⁷

Therefore, we support CMS' proposed changes on payment for dental services under Medicare and urge CMS to continue to expand dental coverage for our rural seniors.

2.b. Proposal To Clarify the Interpretation of Section 1862(a)(12) of the Act and Codify Current Payment Policies for Certain Dental Services

CMS proposes to clarify and codify the agency's interpretation that certain dental services may not be subject to the Medicare's payment exclusion for dental services under Section 1862 (a)(12) of the Social Security Act (SSA, or the Act) because they are "inextricably linked to, and substantially related and integral to the clinical success of, a certain covered medical service."

We strongly support the proposed clarification and codification of existing authority, and we encourage CMS to apply this authority in all settings and clinical circumstances where it is appropriate and further expand its reading of the Act. NRHA regards CMS' prior reading of § 1862(a)(12)¹⁸ of the Act as unnecessarily restrictive and agrees that CMS has more authority under the statute than it has historically wielded. NRHA also applauds the proposal to allow payment to be made, regardless of whether the services are furnished in an inpatient or outpatient setting. Rural hospitals provide a more significant portion of outpatient services compared to inpatient, and this provision ensures that rural seniors can receive dental services without limitations on the care setting. The new proposed changes at 42 C.F.R. § 411.15(i) will increase coverage and ultimately expand access to dental services for our rural seniors.

NRHA supports these proposed changes as interim measures and looks forward to seeing more complete coverage. NRHA asks that CMS work alongside Congress to reduce statutory exclusions on Medicare payment for dental care and promulgate future rules that dental enhance coverage for rural seniors.

2.c.ii. Establishment of a Process To Consider Additional Clinical Scenarios for Future Updates

CMS proposes the establishment of a process within the annual rulemaking cycle by which the agency would review and consider additional clinical scenarios that may fall under this "medically necessary" dental authority. Given the breadth of health issues connected to oral health and proper oral health care, the medically necessary coverage standard must keep up with growing clinical evidence and evolving standards of care to be meaningful to our rural seniors. We strongly support CMS' proposal to implement a process that provides for the future review and addition of new clinical

¹⁶ BUREAU OF HEALTH WORKFORCE, HEALTH RESOURCES AND SERVICES ADMINISTRATION, *Designated Health Professional Shortage Areas Statistics: Third Quarter of Fiscal Year 2022*, 3 (July 1, 2022) <https://data.hrsa.gov/Default/GenerateHPSAQuarterlyReport>.

¹⁷ *Id.*

¹⁸ "[W]here such expenses are for services in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth, except that payment may be made under part A in the case of inpatient hospital services in connection with the provision of such dental services if the individual, because of his underlying medical condition and clinical status or because of the severity of the dental procedure, requires hospitalization in connection with the provision of such services[.]"

scenarios that meet the criteria laid out in CMS' proposed medically necessary dental coverage authority.

2.c.iii. Request for Comment on Dental Services Integral to Covered Medical Services Which Can Result in Improved Patient Outcomes

NRHA recommends coverage for dental services that are so integral to the standard of care for an otherwise covered medical service that the exclusion under § 1862(a)(12) should not apply. First, NRHA recommends coverage for preventive dental services and nonsurgical periodontal treatment for beneficiaries with diabetes. Diabetes is closely related with a number of oral diseases, including periodontitis. Studies have shown that treating periodontitis is associated with improvement in metabolic control, which improves diabetic symptoms.¹⁹ Diabetes impacts almost 30% of adults over the age of 65, and thus dental coverage for diabetic beneficiaries is critical.²⁰ Diabetes prevalence is approximately 17% higher in rural areas than in urban.²¹ NRHA also recommends coverage for preventive dental care for beneficiaries with heart disease. Studies have indicated an association between periodontal disease and cardiovascular diseases and stroke. Periodontal treatment may reduce risk factors for cardiovascular diseases, and thus should be covered. Data from the 2017 Centers for Disease Control and Prevention (CDC) National Health Interview Survey showed a 40% higher prevalence of heart disease among rural residents (14.2%) compared with their counterparts in small metropolitan (11.2%) and urban (9.9%) areas, a gap that has grown over the past decade.²²

CMS is further seeking comment on whether the success of a given surgery is dependent upon eradication of an oral or dental infection. NRHA suggests that CMS cover preventive dental services prior to certain surgeries where there is evidence that such services will reduce the risk of hospital-acquired infections. CMS may also consider this coverage for elective surgeries.

II.M. Medicare Economic Index

The Medicare Economic Index (MEI) is used to update payment limits for rural health clinics (RHCs) under § 1833(f)(2) of the SSA. NRHA appreciates CMS' proposal to rebase and revise the MEI to reflect current market conditions that physicians face. The MEI was last rebased in 2006 and revised in 2014. CMS proposes to rebase the MEI to 2017. These changes amount to a CY 2023 increase of 3.8%, which is one-tenth of a percentage point higher than the 2006-based MEI (3.7%) would be for CY 2023. RHCs owned by a hospital with less than 50 beds are paid their 2020 rate, increased by the

¹⁹ Terry C. Simpson, et al., *Treatment of periodontitis for glycemic control in people with diabetes mellitus*, COCHRANE DATABASE OF SYSTEMATIC REVIEWS (Apr. 14, 2022).

²⁰ American Diabetes Association, *Statistics About Diabetes* (Mar. 22, 2018) <https://diabetes.org/about-us/statistics/about-diabetes#:~:text=Prevalence%20in%20seniors%3A%20The%20percentage,diagnosed%20with%20diabetes%20every%20year.>

²¹ Samuel D. Towne, et al., *Assessing Diabetes and Factors Associated with Foregoing Medical Care among Persons with Diabetes: Disparities Facing American Indian/Alaska Native, Black, Hispanic, Low Income, and Southern Adults in the U.S. (2011–2015)*, 14 INT. J. ENVIRON. RES. & PUBLIC HEALTH 464, 472 (Apr. 2017) <https://www.mdpi.com/1660-4601/14/5/464>.

²² Robert A. Harrington, et al., *Call to Action: Rural Health: A Presidential Advisory From the American Heart Association and American Stroke Association*, 141 CIRCULATION 615, 616 (Mar. 2020) <https://www.ahajournals.org/doi/epub/10.1161/CIR.0000000000000753>.

MEI each year. Independent or provider-based RHCs with more than 50 beds also have their upper payment limits adjusted by the MEI each year. NRHA thanks CMS for rebasing and revising the MEI in a way such that it will reflect more accurate payments to RHCs. Given the inflationary environment and supply chain and workforce challenges that RHCs are facing, NRHA urges CMS to explore its authority to ensure that rural practitioners are reimbursed a rate that reflects the current economic reality.

III.B. Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

2. New Care Management Codes for Chronic Pain Management (CPM) and General Behavioral Health Integration (GBHI)

NRHA supports the addition of new care management codes for chronic pain management and behavioral health integration under HCPCS code G0511. These codes will more accurately capture the time associated with non-face-to-face time than is currently captured in the all-inclusive rate for RHCs and FQHC prospective payment system rate. We generally support RHCs' ability to provide the same suite of services to rural beneficiaries as fee-for-service providers can in a traditional care setting.

However, NRHA notes that the new codes for chronic pain management meet the definition of an RHC encounter. An RHC encounter is defined as a face-to-face encounter between a patient and an RHC practitioner during which a qualified service is furnished. The proposed codes, which require a face-to-face visit for at least thirty minutes with a practitioner, therefore clearly meet the definition of an RHC encounter. NRHA believes that chronic pain management should be billed as an RHC encounter and reimbursed at the RHC all-inclusive rate.

RHCs are paid based on a cost-per-visit methodology subject to certain upper payment limits. Once the RHC files their cost report, an all-inclusive rate is established and the RHC is reimbursed at this rate for every RHC encounter provided throughout the next year. But over the years RHC reimbursement policy has evolved to include a variety of different methodologies and systems patched together. This has led to increasingly complicated RHC billing and coding rules. NRHA encourages CMS to consider a more sustainable payment policy.

III.F. Modifications Related to Medicare Coverage for Opioid Use Disorder (OUD) Treatment Services Furnished by Opioid Treatment Programs

We thank CMS for clarifying that services furnished at OUD treatment program mobile units will be payable under Medicare. Mobile units are a great resource for expanding access to hard-to-reach communities, like rural areas.

NRHA also supports the proposal for opioid treatment programs to utilize audio-only or audio/video technology to initiate opioid use treatment with buprenorphine. A distant site initiation removes burdens for rural beneficiaries that may not otherwise seek buprenorphine treatment. NRHA asks that CMS expand this flexibility by allowing periodic assessments during buprenorphine treatment to be furnished via audio-only technology beyond the end of the PHE. As discussed, rural residents benefit from telehealth, including audio-only visits, and these options should remain available throughout a treatment program. A recent study suggests that PHE telehealth flexibilities increased

use of OUD-related services and decreased medically treated overdoses among Medicare beneficiaries.²³ Expanding access to telehealth OUD services and treatment is paramount for improving rural beneficiaries' outcomes.

NRHA requests that CMS apply this policy to initiate buprenorphine treatment for OUD in other care settings, such as hospital outpatient departments, physician offices, RHCs, FQHCs, and REHs. About two thirds of counties have low or no capacity to provide buprenorphine services in an office setting, with 72% of those counties being rural.²⁴ 36% of counties are considered to have a high need for buprenorphine treatment, and 61% of those counties are rural.²⁵ CMS must explore pathways to use telehealth to increase access to buprenorphine treatment and therefore decrease inequities in the OUD space.

III.G. Medicare Shared Savings Program

NRHA is extremely pleased with proposed changes to the Medicare Shared Savings Program (MSSP). The focus on health equity and supporting new, inexperienced accountable care organizations (ACOs) will incentivize rural provider participation and lead to more rural beneficiaries being in an accountable care relationship. NRHA applauds the proposed advance investment payments, new performance-based risk glidepath options, cap on negative regional adjustments, health equity adjustment on quality performance, and reinstatement of the sliding scale quality performance standard.

NRHA proposes further changes to MSSP to encourage more rural participation. CMS' goal of covering all Medicare beneficiaries in an ACO by 2030 means that CMS must account for underserved communities, like rural, and the capabilities of rural providers to form ACOs. First, NRHA is concerned that, even with the positive sweeping changes to MSSP, rural providers are left on their own to ascertain how to form or join an ACO. Rural providers could join large local health systems; however, NRHA believes that it would better serve rural providers to have their own ACO. Also, leaving rural providers to join larger ACOs on their own assumes that they have the capability to find and make those connections inside and outside of their communities. This is likely not the case for many rural providers.

As such, NRHA urges CMS to consider implementing a national rural ACO for providers without the expertise and resources to connect with other disparate health systems in the region. CMS should further provide technical assistance and be tasked with holding the rural participants accountable under the national ACO. A technical assistance center operated out of CMS would give rural providers a resource to help them find partners and otherwise facilitate the building blocks of starting an ACO.

²³ Mark É. Czeisler, *A Case for Permanent Adoption of Expanded Telehealth Services and Prescribing Flexibilities for Opioid Use Disorder*, JAMA PSYCHIATRY (Aug. 31, 2022)

<https://jamanetwork.com/journals/jamapsychiatry/fullarticle/2795954>.

²⁴ OFFICE OF INSPECTOR GENERAL, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *Geographic Disparities Affect Access to Buprenorphine Services for Opioid Use Disorder* (Jan. 2020), 9 <https://oig.hhs.gov/oei/reports/oei-12-17-00240.pdf>.

²⁵ *Id.* at 10-11.

A national rural ACO would go a long way towards CMS' goal of 100% coverage by the end of the decade.

Second, NRHA urges CMS to go further than providing advance investment payments. The advance investment payments essentially serve as an interest-free loan that will not provide the intended benefits to some ACOs. NRHA believes that some rural ACOs will need upfront positive cash for staffing needs, infrastructure, and addressing social needs rather than money that will be recouped by CMS once savings are achieved. Rural providers especially need such incentives otherwise rural beneficiaries will remain underrepresented in MSSP.

NRHA also calls on CMS to offer MSSP ACOs a hybrid primary care payment model with both population-based payment (PBP) and fee-for service (FFS) components to encourage rural enrollment. The PBP should account for most of a practice's payment and offer the flexibility to optimize the mix of services, as well as support diverse activities practices perform but are not paid for now, such as team-based care, emails, and phone calls. Services including but not limited to hospital visits, and health-critical services like immunizations, would continue to be paid fully fee-for-service, to encourage their delivery. Payment levels for the PBP portion should reflect significant increases over historical prices for the relevant services, to adequately compensate rural primary care providers and allow them to invest the time necessary for addressing patients' mental health and social needs. CMS should adjust PBP payments for patient complexity and socioeconomic status of rural beneficiaries. Both are important as rural beneficiaries typically have more complex health needs and lower socioeconomic status. Because some services may be "invisible" to patients, such as practices' reaching out to social service agencies for patients with complex needs, we suggest using MSSP's waiver authority to remove patient cost-sharing for the PBP payment.

NRHA believes CMS has the authority to make such a hybrid payment option available across Medicare under current law. Specifically, under 42 U.S.C. § 1395jjj(i), CMS has explicit authorization to implement partial capitation or alternative payment methodologies.²⁶ Under 42 U.S.C. § 1395jjj(f), Congress granted the agency certain waiver authorities for the express purpose of implementing MSSP.²⁷

Finally, NRHA would like to flag the loss of traditional Medicare beneficiaries to enrollment Medicare Advantage (MA), and how that could impact rural participation in MSSP. Medicare is approaching the 50% mark for MA enrollment versus traditional Medicare, with MA projected to surpass traditional enrollment next year.²⁸ This is also reflected in rural areas as MA is gaining popularity among rural

²⁶ "If the Secretary determines appropriate, the Secretary may use any of the payment models described in paragraph (2) or (3) for making payments under the program rather than the payment model described in subsection (d)."

²⁷ "The Secretary may waive such requirements of sections 1320a-7a and 1320a-7b of this title and this subchapter as may be necessary to carry out the provisions of this section."

²⁸ Meredith Freed, et al., *Medicare Advantage in 2022: Enrollment Update and Key Trends*, KAISER FAMILY FOUNDATION (Aug. 25, 2022), <https://www.kff.org/medicare/issue-brief/medicare-advantage-in-2022-enrollment-update-and-key-trends/>.



beneficiaries.²⁹ MA beneficiaries are not eligible to be enrolled in an ACO and therefore, as MA continues to grow, the number of rural beneficiaries participating in an accountable care relationship may not reach required numbers for covered lives. NRHA advises CMS to consider the implications of growing MA enrollment in its approach to both MSSP and MA.

Thank you for the chance to offer comments on this proposed rule and for your consideration of our comments. We very much look forward to continuing our work together to ensure our mutual goal of improving quality and access to care for rural residents. If you would like additional information, please contact Alexa McKinley at amckinley@ruralhealth.us or 202-639-0550.

Sincerely,

A handwritten signature in black ink, appearing to read "Alan Morgan", is written over a light gray dotted grid background.

Alan Morgan
Chief Executive Officer
National Rural Health Association

²⁹ Mina Shrestha, et al., *Medicare Advantage Enrollment Update 2021*, RUPRI CENTER FOR RURAL HEALTH POLICY ANALYSIS (Sept. 2021) <https://rupri.public-health.uiowa.edu/publications/policybriefs/2021/Medicare%20Advantage%20Enrollment%20Update%202021.pdf>.

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Attachment: Response to Request for Information on Medicare Part B Payment for Services Involving Community Health Workers

NRHA advocates for CMS to explore pathways for community health workers (CHWs) to be paid under Medicare Part B. Rural residents face many barriers to health care access, and CHWs can serve as the bridge between rural patients and needed health services.³⁰ Reimbursement under Medicare for CHW services would help to create more sustainable CHW funding systems and make CHWs even more valuable for rural communities. However, Medicare is a national program that may not fit within existing state CHW models. NRHA notes that CMS must take a thoughtful approach to incorporating CHW services into Medicare so as to not disrupt the existing and successful frameworks in states and maintain the valued community-based aspect of CHW work. Currently, CHW frameworks and policies vary state by state and are associated with a state Medicaid program in some instances.

Certification and licensing

Among states, CHW certification varies, if it exists. Thirteen states operate state certification programs for CHWs, and eight states have privately-run certification programs, either through independent credentialing boards or CHW associations.³¹ Not all states with certification programs require that CHWs become certified. For example, Maine does not have a certification program but encourages CHWs to take a core competency course along with topic-specific courses. But some states do compel certification for reimbursement purposes.³² Illinois mandates CHW certification in order to submit claims to Medicaid fee-for-service or managed care organizations (MCO), yet certification is not needed when CHWs are paid through MCO administrative dollars.³³

Per Medicare regulations,³⁴ “auxiliary personnel” are those who work under the supervision of a physician and meet any applicable state licensure requirements. NRHA recommends that CMS allow states to continue to develop and operate their own certification and licensing process for CHWs rather than implement Federal licensure regulations or a nationwide standard. NRHA asks that CMS consider all existing state certification procedures to meet the licensing requirement in 42 C.F.R. § 410.26(a)(i).

However, because many states do not have a mandated CHW certification or licensing process, Medicare reimbursement would not be equitable across states. NRHA is concerned that CHWs would be shut out from reimbursement in states that have not developed or implemented certification for CHWs. CMS must ensure that states without CHW licensing may receive reimbursement regardless

³⁰ See generally, Kailyn Dorhauer Mock, et al., *Community Health Workers: Recommendations for Bridging Healthcare Gaps in Rural America*, NATIONAL RURAL HEALTH ASSOCIATION (Feb. 2017) https://www.ruralhealth.us/NRHA/media/Emerge_NRHA/Advocacy/Policy%20documents/Community-Health-Workers_Feb-2017_NRHA-Policy-Paper.pdf.

³¹ Association of State and Territorial Health Officials, *State Approaches to Community Health Worker Certification* (June 12, 2022) <https://www.astho.org/topic/brief/state-approaches-to-community-health-worker-certification/>.

³² *Id.*

³³ National Academy for State Health Policy, *State Community Health Worker Models* (Dec. 2021) <https://www.nashp.org/state-community-health-worker-models/>.

³⁴ 42 C.F.R. § 410.26(a)(1) (2021).

and also have the appropriate technical assistance to develop and implement certification so that CHWs in some states are not unfairly cut out of Medicare reimbursement.

Reimbursement

As of December 2021, fifteen states reimbursed CHW services through Medicaid.³⁵ For example, Maine does not have a system in place for fee for service reimbursement, but CHWs are still reimbursed through a Medicaid program called the Medicaid Community Care Teams Program.³⁶ This is a per member per month model of payment. Other states, like Michigan, reimburse CHW services through Medicaid MCOs and fee for service programs.³⁷ Twenty-seven states do not have Medicaid reimbursement for CHWs.³⁸ States without Medicaid reimbursement would benefit from a Medicare reimbursement scheme.

As discussed in terms of certification, CMS must be mindful of the variation in state CHW certification procedures when considering how to implement Medicare reimbursement for CHWs. Recognizing existing state certification to consider CHWs auxiliary personnel is crucial. States that lack certification should still be eligible for CHW reimbursement through Medicare.

One up-and-coming model of CHW reimbursement involves clinical organizations, like hospitals, contracting with community-based organizations (CBOs). Many CHWs work at CBOs and these settings face more challenges with reimbursement than clinical settings. Relationships between hospitals and CBOs are still growing in states and are consequently working out kinks in the process. Nonetheless, it is a promising model that provides payment to CBOs. CMS should examine this and other possibilities for reimbursing CHWs in CBOs as these tend to be the primary employer of CHWs.

Additionally, Maine is carrying out a model for integrating CHWs in primary care. By April 2024, all primary care practices in Maine will be required to use CHWs in order to bill Medicaid. Where feasible, CMS could model a framework after this for physicians paid under PFS. NRHA acknowledges that this model may not be appropriate for all primary care physicians and would likely require an extensive rollout period. This is a valuable example of how to grow CHW services and utilize them to fill in gaps in care and address SDOHs that practitioners otherwise do not have the time or capability to tackle.

Overall, CMS should work within its statutory and regulatory authority to incorporate CHWs into Medicare reimbursement under the PFS. We have heard that providers are unwilling to hire and utilize CHWs without reimbursement, which is especially troublesome for states that do not reimburse CHWs through Medicaid. This is especially true for rural providers that operate under tight margins and cannot hire health care professionals without reimbursement. One step toward expanding CHWs' role in the health workforce is to ensure providers receive reimbursement for CHWs.

³⁵ National Academy for State Health Policy, *supra* note 33.

³⁶ *Id.*

³⁷ *Id.*

³⁸ *Id.*

Supervision

In many cases, CHWs are not employees of a physician or employees of entities that employ physicians. CHWs may work alongside physicians in a clinical setting like a hospital or health system or a health center such as an FQHC. While we are seeing a growth of CHWs in clinical spaces, the majority of CHWs are employed by a CBO or a faith-based organization. For example, in Vermont, the majority of CHWs work in CBOs, with some in hospitals and FQHCs. For Vermont in particular, CHWs do not work at every FQHC, but about half of the state's FQHCs employ a CHW. Just as the care setting varies, so too does supervision of CHWs. Generally, supervision would not meet Medicare standards for direct supervision by a physician or other practitioner under 42 C.F.R. § 410.32(b)(3)(ii).

Again, supervision also varies by state. Most states do not have requirements surrounding supervision. For states with supervision mandates, the supervisor is often not required to be a practitioner, or the supervisor rules vary by care setting.³⁹ Some states may provide supervision training, but it is largely optional.⁴⁰ CHWs, in some cases, may have clinical supervision, such as by a registered nurse. But CHWs are also often supervised by other CHWs, behavioral health professionals, or health care administrators. For example, CHWs in Vermont tend to be supervised by program managers or directors. Even in a clinical setting, CHWs in Vermont are less likely to be supervised by a physician and more likely to work under a social worker or other behavioral health professional.

One concern with CHWs as auxiliary personnel is the appropriateness of physician or other practitioner supervision over CHWs. In its RFI, CMS specifically asks whether supervision of CHWs would meet the definition of direct supervision. Under § 410.32, direct supervision in an office setting means that a physician is immediately available. Although required for billing as an auxiliary personnel incident to physician's services, physician supervision may not be the best approach for CHWs. Physicians may not understand the role and purpose of CHWs as well as other supervisors, like other CHWs and behavioral health professionals. Additionally, considering the health care workforce shortage facing rural communities, physicians likely do not have the time to devote to overseeing and meeting with CHWs.

Preventive services

CHWs are often involved in preventive services, some of which would be considered medically reasonable and necessary. Maine uses CHWs for a program funded by the Centers for Disease Control and Prevention to prevent and delay the onset of diabetes.⁴¹ CHWs are also used for work with healthy eating, physical activity, and other SDOHs that can prevent chronic diseases. CHWs aid in asthma prevention and control by performing household screenings for environmental factors that can cause asthma or asthma triggers. CHWs are integral to accessing resources for community

³⁹ *Id.*

⁴⁰ *Id.*

⁴¹ CENTERS FOR DISEASE CONTROL AND PREVENTION, *State, Local, and National Partner Diabetes Programs* (Aug. 3, 2021) <https://www.cdc.gov/diabetes/programs/stateandlocal/funded-programs/dp18-1815.html#:~:text=About%20the%20Program&text=This%205%2Dyear%20cooperative%20agreement.%2C%20heart%20disease%2C%20and%20stroke>.

members and facilitating health education. For example, CHWs connect patients to early cancer screenings and have played a large role in COVID-19 education and resource connection as well.

In Vermont, CHWs are involved in the Support and Services at Home (SASH) Program.⁴² Nurses and CHWs are assigned to housing sites and work with individuals with disabilities and the elderly. SASH employs over 70 CHWs across Vermont where they address medical and oral health needs and chronic conditions like diabetes and hypertension. Beyond SASH, CHWs in Vermont play a large role in health advocacy and education in their communities. CHWs also connect residents to preventative screenings, dental services, and mental and behavioral health services.

NRHA thanks CMS for its Request for Information on CHWs and hopes to see appropriate Medicare reimbursement for much needed CHW services in rural areas.

⁴² See generally, Support and Services at Home, *Learn About SASH*, <https://sashvt.org/learn/>.