

Before the
FEDERAL COMMUNICATIONS COMMISSION
Washington, D.C. 20554

In the Matter of) WC Docket No. 18-213
Promoting Telehealth for)
Low-Income Consumers)

COMMENTS OF THE STATE OF COLORADO

August 29, 2019

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COLORADO
Governor Jared Polis

August 29, 2019 Ajit Pai, Chairman
Federal Communications Commission
445 12th Street, SW Washington, DC 20554

Chairman Pai,

The State of Colorado (“Colorado”) convened a group of stakeholders from state agencies and community leaders focused on advancing health with technology and policy who collaboratively worked to draft Colorado’s comments for the Federal Communications Commission’s (FCC) Notice of Proposed Rulemaking, WC Docket No. 18-213, Promoting Telehealth for Low-Income Consumers. First, Colorado applauds the FCC for its forward-looking vision on the importance of linking Internet access with improved health outcomes through the use of telehealth services. Colorado supports the FCC’s desire to have flexible Connected Care Pilot projects that provide latitude for applicants to determine specific health conditions and geographic areas that will be the focus of the proposed projects.

The State agrees with the Pilot’s goals of improving health outcomes while reducing costs and seeking ways in which the Universal Service Fund can support telehealth efforts. To best meet the intent of flexibility and latitude, and the program goals, it is critical to have a “framework” that fosters success. The framework may be as important as the definitions of telehealth, health conditions, and Health Care Providers.

The term “health” has evolved from the traditional physical health to include mental health, and now includes such phrases such as “Social Determinants of Health” and “Connected Care.” Colorado believes the term health should be broadly construed to include recognized and accepted health terms and the definition of who is eligible to provide the services should be linked to the service itself.

The State agrees that qualifying Pilot projects should reflect “health conditions” that typically require at least several months or more to treat. In terms of defining health conditions, the State recommends that the rule remain flexible for applicants to identify health related conditions which would be improved by the use of telehealth. For example, aging-in-place brings quantitative benefits and measurable cost-savings and as well, brings qualitative benefits of remaining at home where almost all people, especially seniors desire to live. Parallel to aging-in-place, in Colorado end-of-life directives can be completed remotely via telehealth services and would be a worthwhile Pilot project. directives can be completed via telehealth services and would be a worthwhile Pilot project.

One of the outcomes that the FCC seeks is closer collaboration with the Center for Medicare & Medicaid Services (CMS) and the Office of the National Coordinator (ONC) for Health Information Technology. CMS (like the FCC) recognizes the importance of authorizing pilot or demonstration projects that present opportunities to institute reforms that go beyond just routine medical care and focus on evidence-based interventions that drive better health outcomes and quality of life improvements. CMS has approved several Colorado initiatives such as Home and Community Based Services and the KidneyX challenge that enable patients to remain at home through the use of remote health services. These initiatives would be great candidates for a Connected Care Pilot project by providing Internet access solutions which would greatly enhance the provision of health services.

Colorado recommends that the FCC and CMS jointly identify complementary programs and reporting requirements that would reduce regulatory burdens while enhancing efforts to guard against fraud, waste and abuse. Similarly, just as the FCC has extensive experience with the barriers facing low income in terms of Internet access, CMS and ONC have that same level experience with health care barriers faced by low-income rural patients and health care providers. We recommend that the FCC include representatives from CMS and ONC on the evaluation team as they are the entities that have extensive experience with low-income health programs and barriers.

The State generally agrees with the 85% discount yet believes that the FCC should cap the amount a patient would be required to pay which would avoid insurmountable barriers. To promote competition, we believe that non-eligible telecommunications providers should be able to provide Internet services to health care providers and patients.

In summary, Colorado recommends that the FCC adopt an outcome-based approach for the Connected Care Pilot program which rewards innovation and collaboration.

Respectfully,

A handwritten signature in blue ink that reads "Jared Polis". The signature is written in a cursive, flowing style.

Jared Polis Governor

A handwritten signature in blue ink that reads "Dianne Primavera". The signature is written in a cursive, flowing style.

Dianne Primavera Lt. Governor

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INTRODUCTION AND SUMMARY

The State of Colorado (“Colorado”) appreciates the opportunity to submit comments on the Federal Communications Commission’s (FCC) Notice of Proposed Rulemaking, WC Docket No. 18-213, *Promoting Telehealth for Low-Income Consumers*, adopted July 10, 2019 and published in the Federal Register on July 29, 2019. (“Notice”). The comments are a result of a collaborative effort coordinated by the Governor’s Office of eHealth Innovation consisting of input from stakeholders across Colorado that includes the Lt. Governor’s Health Cabinet, eHealth Commission, Office of Information Technology, Department of Health Care Policy and Financing, Department of Human Services, Office of Behavioral Health, Office of Broadband, Colorado’s Regional Health Information Organization, Quality Health Network, Prime Health, Colorado Hospital Association, Colorado Rural Health Center, Colorado Commission of Indian Affairs, rural community health providers, and technical leaders across the State.

Colorado applauds the FCC for its forward-looking vision on the importance of linking Internet access and improved health outcomes through the use of remote and telehealth services.¹ As the Notice correctly states, “advances in telemedicine are transforming health care from a service delivered solely through traditional brick and mortar health care facilities to connected care options delivered via a broadband Internet access connection directly to the patient’s home or mobile location.”² Similarly the FCC recognizes that “[d]espite the numerous benefits of connected care services to patients and health care providers alike, patients who cannot afford or who otherwise lack reliable, robust broadband Internet access connectivity are not enjoying the benefits of these innovative telehealth services.”³

Colorado supports a flexible “Connected Care” Pilot program that the Notice describes as giving health care providers “some latitude to determine specific health conditions and geographic areas that will be the focus of the proposed projects.”⁴ We want to emphasize the terms “flexible” and “latitude” as the State believes that the success of meeting the FCC’s stated goals may be accomplished through new and existing projects that leverage ongoing efforts for low-income patients and/or veterans and/or projects connected to tribes.

One of the outcomes that the FCC seeks is closer collaboration with the Center for Medicare & Medicaid Services (CMS) and the Office of the National Coordinator (ONC) for Health Information Technology (HIT). CMS (like the FCC) recognizes the importance of authorizing pilot or demonstration projects and waivers that present opportunities to institute reforms that go beyond just routine medical care, and focus on evidence-based interventions that drive better health outcomes and quality of life improvements.⁵ Additionally, CMS’s Center for Medicare and Medicaid Innovation (CMMI) authorizes projects that test new models for

¹ The use of the words “Internet” or “Broadband” as used in the States comments are meant to convey generally accepted and recognized terms for the type of “service” used to provide telehealth health care services. The words “Internet” or “Broadband” are not intended to make a legal distinction between “telecommunications” or “enhanced” or “information” services.

² Notice of Proposed Rulemaking, WC Docket No. 18-213, Promoting Telehealth for Low-Income Consumers, at para 1.

³ Ibid.

⁴ Ibid, at para. 7.

⁵ <https://www.medicaid.gov/medicaid/section-1115-demo/about-1115/index.html>

paying for and delivering health care and at the same time, changing the way Medicare and Medicaid pay for health care.⁶ One of the objectives of the CMMI program is rate reform which mirrors the FCC's desire to positively impact reimbursement for telehealth services.

Colorado has an ONC KidneyX challenge grant with a goal of improving the lives of the 850 million people currently affected worldwide by accelerating the development of drugs, devices, biologics and other therapies across the spectrum of kidney care including: Prevention, Diagnostics and Treatment.⁷ This is an example of a worthwhile proposal for a connected care Pilot project that promotes remote and telehealth services. It further demonstrates how the FCC can leverage dollars from diversified streams of federal and state funding (without "double dipping") for projects that span over several agencies (FCC, CMS, Veterans Administration, etc.) and which avoid duplication while aligning with federal goals and strategic plans.

Colorado has several CMS approved Home and Community Based Services projects that promote and engage in Assisted Daily Living activities using remote services. Our experience is that while these services really help patients' ability to remain at home, some services suffer due to lack of Internet access by patients and HCPs. A connected care Pilot project providing Internet access solutions could greatly enhance the provision of services for these patients and their health care providers.

CMS's approval process for demonstration projects and waivers, and CMMI initiatives, is rigorous. CMS has strict rules and regulations for applications and reporting requirements including detailed outcomes, measurements, work plans, ongoing reporting of costs and quality measures, and evaluations. The regulations also require periodic discussions with CMS officials on program operations, lessons-learned, midcourse corrections (where needed), and final evaluations. Similar to FCC programs, a key component of the CMS program requirements is to guard against fraud, waste, and abuse. Although all of these projects must cost the federal government equal to or less than what the federal government would pay for traditional

⁶ <https://innovation.cms.gov/>

⁷ <https://www.hhs.gov/cto/initiatives/kidneyx/index.html>

treatment, the projects can result in considerable cost savings. In many cases, the traditional treatment would be the patient needing significant home health aide services or going into a long-term care facility at costs that average between \$48,000 to \$58,916 per year in Colorado.⁸ The costs of individual telehealth services vary, yet Medicare and Medicaid reimbursement amounts are much less and usually average at most, \$65.00 per encounter.⁹

The Notice specifically invites comments on how the FCC can collaborate with CMS and ONC. Colorado recommends that the FCC and CMS/ONC jointly identify complementary programs and reporting requirements. The two agencies can identify reporting requirements or portions of reports that each agency compels projects to report on, such as assurances against fraud, waste, and abuse; or measuring the success of programs including cost-effectiveness. The FCC could allow applications that involve CMS projects, such as Home and Community Based Services, to submit their approval letter, project plans, and reports. That type of joint collaborative effort also results in reduced administrative burdens for HCPs while meeting both agencies' goals and policies to reduce fraud, waste and abuse. Similarly, CMS may find that elements reported to the FCC may satisfy some of its program requirements.

We agree that the Pilot project goals identified by the FCC are both laudable and practical. To best meet the intent of flexibility and latitude along with the program goals, it is critical to have a "framework" that promotes success. The "framework" becomes perhaps as important as the definitions of telehealth, health conditions, and HCPs. We recommend that the FCC adopt an outcome-based approach where applicants submit their proposed methodology for how progress toward meeting the goals will be measured. The methodologies chosen should be

⁸ See <https://www.genworth.com/aging-and-you/finances/cost-of-care.html> listing the average cost of home health aide services for 44 hours per work at \$58,916 a year and a semi-private assisted living room at \$48,000 a year in Colorado for 2018 with expected growth rates of at least 3-4% per year.

⁹ See, CMS final 2019 Physician Fee Schedule and Quality Payment Program, opening the door to reimbursement for connected care services that enable providers to manage and coordinate care at home. <https://mhealthintelligence.com/.../cms-to-reimburse-providers-for-remote-patient-monitoring>.

sufficiently defined to create trust in the project and its outcomes which can be judged during the evaluation process.

I. Colorado believes the term “health” should be broadly construed to include recognized and accepted “health” terms and services provided by an expanded view of professionals.

17. The State agrees that qualifying Pilot projects should reflect “health conditions” that typically require at least several months or more to treat. The Notice expressly identifies diabetes, kidney disease, heart disease, and stroke recovery as qualifying for the Pilot. While these chronic conditions are worthy of inclusion, the State recommends that the rule remain flexible for applicants to identify additional health related conditions which would be greatly served through remote or telehealth efforts. For example, aging-in-place brings quantitative benefits and measurable cost-savings and qualitative benefits of remaining at home where almost all people, especially seniors desire to live. Parallel to aging-in-place, end-of-life directives can be completed via telehealth services and would be a worthwhile Pilot project. The final rule should include the identified health conditions along with “an applicant may identify a particular need for low-income patients or veterans or tribes that would greatly benefit from remote and telehealth services that meet the intent of the rule.”

21. Colorado generally agrees that the definition of “telehealth” includes a wide variety of remote health care services beyond the doctor–patient relationship including services provided by nurses, pharmacists, or social workers. The term “health” has evolved from the traditional physical health to include mental health, and now includes such phrases such as “Social Determinants of Health” and “Connected Care.” Assisted Daily Living activities are another example of “health.” Evidence-based research demonstrates that “medical care accounts for only 20 percent of the factors driving outcomes and costs while factors such as health behaviors, social and environment, and physical environment account for 80 percent of wellbeing.”¹⁰ Given that a goal of the Pilot is to improve health outcomes, it is logical to view health through the lens of whole health and patient-centric care.

¹⁰ See CMS MeT Report: Integrating Social Determinants of Health (SDH) and Medical Data using Electronic Health Records (EHR) to Improve Patient Care and Health Outcomes: The

Colorado believes the term “health” should be broadly construed to include recognized and accepted “health” terms and services provided by professionals such as social workers or home and community based services providers. The State recommends that the rule allow applicants to submit applications requesting approval for innovative “health” services provided through remote broadband technology (telehealth) by appropriate Health Care Providers and professionals.

We agree “telemedicine” services are a subset of telehealth services that use broadband technologies to support the delivery of medical, diagnostic, and treatment-related services. Although the Notice indicates that telemedicine is usually performed by doctors, Colorado believes that telemedicine delivered by additional health care and other professionals should be allowed under the Pilot.

Similar to the many comments the FCC received, Colorado expressly supports funding both fixed and mobile broadband for connected care.¹¹

The State concurs that “connected care” is a subset of telehealth that focuses on delivering remote medical, diagnostic, and treatment-related services directly to patients outside of traditional brick and mortar facilities. Similar to our comments for the definition of telehealth, the term “connected care” should follow the expanded definition of telehealth which includes “health” related services such as Social Determinants of Health, and Assisted Daily Living activities under the Home and Community Based Services program.

The Notice asks if the FCC should place any additional qualifiers on connected care to ensure that the Pilot program is focused on medical services delivered directly to patients outside of traditional medical facilities through broadband-enabled technologies. Given that the applications must demonstrate how telehealth is the primary focus of the Pilot and that the funds are used to pay for Internet access, adding qualifiers may have unintended consequences that could prevent patients and HCPs from participating in a telehealth Pilot project.

Protocol for Responding to and Assessing Patients’ Assets, Risks, and Experiences (PRAPARE) Assessment Tool, December 14, 2018, pg. 5.

¹¹ Notice of Proposed Rulemaking, WC Docket No. 18-213, Promoting Telehealth for Low-Income Consumers, at para. 19.

37. The State agrees that the Health Care Providers identified in the Notice should be eligible to participate in the Pilot Program. We also recognize that have a specified list has the added benefit of giving a single uniform definition used for the Healthcare Connect Fund and the Veterans Administration. Given the goal of the Pilot is to expand the use of telehealth services which the FCC expressly recognizes “includes a wide variety of remote health care services beyond the doctor–patient relationship”¹² Colorado recommends the definition of who is eligible to provide the services should be linked to the service itself. For example, end-of-life decisions may involve an attorney who has a long-established relationship with a patient. If an HCP links with a legal services professional to offer this type of telehealth service, the rule should permit this as a Pilot project. The rule should indicate that additional health services that are linked to or in partnership with an HCP are permitted to be included in a proposed project. This is consistent with the stated goals of increasing the use of telehealth and connected care.

Similarly, if a provider is enrolled as a Medicare provider with CMS, or as a Medicaid provider with a state, or licensed as Home and Community Based Services providers are in Colorado, they should be eligible to participate in the Pilot project. CMS and state Medicaid agencies (as well as the VA and Tribes) have established formal procedures, including credentialing requirements.¹³ Many enrolled providers are included in the list of HCPs in the draft rule; yet specifically stating that enrolled or licensed providers are eligible to participate in the Pilot serves to reduce administrative burdens while guarding against fraud, waste, and abuse.

II. Colorado agrees that the FCC should not limit the number of projects but should adopt a reasonable threshold above which applicants would need to provide further rationale.

28.36. The Notice proposes an initial \$100 million 3-year Pilot program. Colorado would naturally prefer a higher level of funding for this important Pilot Program. Telehealth is a proven technology which improves health outcomes with costs that continue to drop in real

¹² Notice of Proposed Rulemaking, WC Docket No. 18-213, Promoting Telehealth for Low-Income Consumers, at para. 37.

¹³ <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/EnrollmentApplications.html>

terms as broadband technology and access become more fully available throughout the country, particularly in rural areas. We do recognize, however, that the funds for the Pilot must be balanced with other Rural Health Care (RHC) programs and generally agree with the \$100 million 3-year funding approach as the initial path toward the consideration of a permanent connected care program. The State encourages the FCC to adopt a flexible approach to the ramp-up and wind-down periods based on the Pilot project application.

33. Colorado agrees with the FCC that it should not limit the number of Pilot projects nor adopt a uniform \$5 million funding amount per project. (The State similarly supports not spending all of the Pilot funds on a few large projects.) If the FCC establishes a ceiling, the Notice seeks comments on the appropriate maximum funding. Rather than establishing a ceiling for a single project, we recommend that if a proposed request exceeds a certain threshold (perhaps \$10 million) that the applicant provide additional justification and documentation to support the request. (For example, the Pilot is a multi-state project; involves a very large volume of patient participants; or includes a cost-benefit-analysis to demonstrate substantially lower costs and an exponentially increased amount of savings or health benefits.) Having that flexibility with conditions would provide assurances should an applicant make a large funding request.

III. The laudable FCC goals support the expansion of mechanisms used to measure progress toward meeting the goals and cost savings.

78-92. Colorado believes that the FCC has chosen four laudable goals for the Pilot. Each of the goals is linked to the notion of connected care which has at its roots, the notion of whole-person and person-centric care designed to meet the health needs of individuals wherever they are located.

78. 81. Goal No. 1, *Improving health outcomes through connected care through telehealth* can enable HCPs to more easily engage patients in daily management; increase the likelihood patients will seek out medical care and follow a prescribed course of treatment; reduce emergency department visits; and reduce hospital admissions or readmissions. Well researched and accepted studies and reports demonstrate that these approaches improve health outcomes not only by avoiding costs and patient lost productivity, but also by increasing

patient satisfaction by permitting the patient to seek health services in more convenient locations, including their own homes.¹⁴ Certain types of specialists, and indeed primary care providers are scarce, especially in rural areas in Colorado. Expanding telehealth brings more effective and efficient provision of services which in turn improves health outcomes.¹⁵

82. 83. Colorado agrees with the list of “burdens” (e.g., out-of-pocket transportation costs and missed work time) the FCC has identified under Goal 2. *Reducing health care costs for patients, facilities, and the health care system.* Reducing the burden of out-of-pocket transportation costs and missed work or school time creates savings for patients, and lowers costs for programs such as the Veterans Administration, Medicare, and Medicaid.

90. It has been Colorado’s experience that low- income consumers do face budget constraints that are not adequately addressed by existing Rural Health Care Programs which prevent them from adopting connected care services. The fact that Medicaid and generally, the Veterans Administration (VA) do not pay for Internet access for patients presents a financial burden for low-income patients.¹⁶ The cost of *basic* consumer Internet service in Colorado ranges from approximately \$40 to \$70 per month depending on the type of service purchased.¹⁷ Although low-income consumers may be eligible for a \$9.25 lifeline discount on their Internet service rate, FCC rules require low-income consumers to choose between a discount on telephone service or Internet service.¹⁸ Many consumers need and want both types of service but simply cannot afford them.¹⁹

30.31. In terms of an appropriate discount, Colorado believes that 85% generally strikes the right balance as it is reasonable to have HCPs and patients pay a portion of the charges and have a stake in complying with the intent of the rule. Having said that, it is important to cap the

¹⁴ Ibid. at para. 15.

¹⁵ Ibid at para. 57.

¹⁶ The record indicates that the VA’s tablet program, which provides patient broadband connections for a small fraction of veterans who receive care through the VA, is the only federal agency program that currently funds patient broadband connections specifically for connected care. Ibid at para. 19.

¹⁷ <https://www.whistleout.com/Internet/United-States/Colorado>

¹⁸ <https://www.fcc.gov/general/lifeline-program-low-income-consumers>

¹⁹ See, e.g., <https://www.consumerreports.org/cro/telecom-services/buying-guide/index.htm>

maximum amount that patients must pay to avoid situations where the financial burden becomes an obstacle for participation. The FCC with its vast experience with Internet rates is in the best position to determine what that monthly cap should be.

HCPs who must travel to their offices or hospitals, or make home visits would save similar transportation and time costs. There is a strong emphasis in many states, including Colorado, to allow citizens to age-in-place—to remain in their homes longer (where they want to be) while remaining safe and as healthy as possible.²⁰ The use of telehealth greatly promotes this goal along with avoiding the considerable expense of moving to a long-term or assisted care facility which may be many miles from an individual's home, family, friends, and support network. Savings can be measured by the length of time patients remain in their homes multiplied by what it would cost in the long term facility (minus telehealth service costs). Colorado recommends that the FCC identify aging-in-place as a mechanism to measure the progress of meeting Goal No. 2, and indeed, all four goals as it improves health outcomes, connected care everywhere and can have a positive influence on the Universal Service Fund (USF) improving telehealth initiatives.

85. Goal No. 3, *Supporting the trend towards connected care everywhere*, is significantly benefited by having the USF support broadband which promotes access to health care services for patients outside of the confines of brick-and-mortar medical facilities. Low-income rural patients are forced to spend time and money on transportation and travel to facilities that may be miles and hours away, likely resulting in poorer health outcomes as appointments are not made or are missed. Some consumers may not have transportation available to them in which case, Medicaid or other low-income programs may have to provide transportation services at much greater costs.

²⁰ See, e.g., Survey showing that 94% of respondents of 1,000 age 55-75 home owners indicated that they want to age in place and that modern technology is critical to meeting that desire. Home Instead, Inc., Nov. 21-30, 2018.

90. During the early stages of the federal Meaningful Use Program²¹ health care provider surveys indicated that the costs of implementing Electronic Health Records (EHRs) was a significant financial burden and a primary reason for not employing EHRs. The Meaningful Use Program (now termed the Promoting Interoperability Program) dramatically increased the number of HCPs and the use of EHRs and associated technology by providing 100% federal funding (up to certain limits) for implementation of EHRs.²² The Promoting Interoperability Program provides enhanced federal funding (90% Federal match) for connecting EHRs to Health Information Exchanges which house clinical data, and for appropriate administrative costs.²³ The history of the Promoting Interoperability Program demonstrates that a concerted effort to fund electronic exchange of clinical data among HCPs promotes overall federal and state goals of improving population and individual health outcomes. The proposed FCC Pilot can greatly enhance other federal efforts, such as the CMS Medicaid and Medicare demonstration and waiver programs, through collaborative efforts that include telehealth services. The first step was to get the EHRs to HCPs; now is the time to get the Internet access and connected care services to HCPs and their patients.

78. Similarly, Goal No. 4, *Determining how USF funding can positively impact existing telehealth initiatives*, is linked to the other three goals and can be measured both in terms of quantifying the reduction in burdens (transportation costs; reduced Emergency Department use and hospital admissions) and by qualitative and quantitative measurements of the length of time patients can remain at home vs. moving to a more expensive long-term facility. Patient satisfaction surveys have shown that aging-in-place with Internet and telehealth services provides peace of mind for the individual, families, and caregivers.²⁴

92. The State believes that Pilot funding will enable patients and HCPs that would not otherwise have access to telehealth by opening up telehealth to new geographic areas and

²¹ <https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/index.html?redirect=/ehrincentiveprograms/> and 42 CFR Part 495 – Standards for the Electronic Health Record Technology Incentive Program.

²² Ibid.

²³ Ibid.

²⁴ See FN 18.

attracting new funding.²⁵ Providing funding for Internet access for telehealth has the ancillary benefit of expanding the “take-rate” of individuals with Internet access thereby helping to reduce the costs of providing Internet in rural areas.

IV. The FCC should adopt an outcome based approach to how progress is measured—clinical trials are not necessary.

40.44. Requiring *all* HCPs to have prior experience with telehealth and long-term patient care may artificially restrict potentially high-value low-cost projects that could produce meaningful results for low-income and/or rural patients. For consortiums of HCPs and other professionals, the individuals bring their own experiences to the table. Some may have prior telehealth while others have experience in long-term patient care. Rather than requiring all HCPs to have both, it is more appropriate to have a “mix” of professionals who bring their own strengths and experience to the project. The FCC can consider the merits of the application during the evaluation process.

96. The Notice seeks comments on whether the proposed eligible HCPs are sufficiently well versed in medical research methods to evaluate health outcomes of connected care. It also asks whether the Pilot should be conducted using randomized controlled trials. Generally, randomized controlled trials are studies in which people are allocated at random (by chance alone) to receive one of several clinical interventions. One of these interventions is the standard of comparison or control. The control may be a standard practice, a placebo (“sugar pill”), or no intervention at all. Random control trials have the benefits of avoiding selection bias and have high statistical validity if samples are large enough to provide meaningful data.²⁶ However, power calculations might demand vast sample sizes and trials which test for efficacy may not be widely applicable. Trials which test for effectiveness are larger and more expensive. Under Medicaid rules, health care providers must provide services to “any willing patient.” It would be difficult to meet this requirement using a clinical trial.²⁷ The question may

²⁵ See, e.g., Digital divide persists even as lower-income Americans make gains in tech adoption, by Monica Anderson and Madhumitha Kumar, Pew Research Center, May 9, 2019.

²⁶ See, e.g., <https://researchguides.library.tufts.edu/c.php?g=249122&p=1658766>

²⁷ See, 47 CFR § 54.642(c).

become “when does perfection becomes the enemy of the good?” Studies and clinical information demonstrate that there are many health benefits that are generally accepted and which a formal clinical trial study may not reap any significant information that would outweigh the “costs” of having a formal clinical trial.²⁸

The stated goals do not require “clinical trials.” HCPs are automatically given Medicaid and Medicare, VA, and tribal claims and can use them to measure cost reductions such as reduced transportation costs, or a decrease in missed appointments, reduced Emergency Department visits, and avoided hospital admissions. More important, the data can be submitted in aggregate as de-identified data to avoid Health Insurance Portability and Accountability Act (HIPAA) or other privacy law concerns.

Medicare and Medicaid demonstration projects and waivers already include essential parameters of meeting as least budget neutrality.²⁹ If the concern is costs, CMS monitors budget neutrality throughout a demonstration project period and also performs a formal adjudication at the end of the demonstration period to determine whether the state’s actual spending has remained within the specified limit.³⁰

Other measures such as patient satisfaction can be achieved through the use of patient and family surveys, as well as HCP surveys and observations.

We recommend that the FCC adopt an outcome-based approach where applicants submit their proposed methodology for how progress toward meeting the goals will be measured. The methodologies chosen should be sufficiently defined to create trust in the project and its outcomes.

²⁸ See, e.g., *Factors associated with clinical trials that fail and opportunities for improving the likelihood of success: A review*. David B. Fogel, Contemporary Clinical Trials Communication, August 7, 2018. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6092479/>

²⁹ CMS’s determination that a demonstration is expected to be budget neutral is based on forecasts, using reasonable projections of future spending and enrollment trends. SMD # 18-009 RE: Budget Neutrality Policies for Section 1115(a) Medicaid Demonstration Projects August 22, 2018 State Medicaid Director letter.

³⁰ Ibid.

V. To promote market based approaches, the FCC is correct not to require HCPs to contract with only ETCs.

69. Generally, the State agrees with the premise that requiring competitive bidding processes as used under the HCF Program leverages market forces allowing scarce universal service funds to go further. The HCF rules require HCPs to select the most cost-effective bid defined as “the method that costs the least after consideration of the features, quality of transmission, reliability, and other factors that the health care provider deems relevant to choosing a method of providing the required health care services.”³¹ The current definition of “cost-effectiveness” used by the RHC program is sufficiently narrow to prevent fraud, waste, and abuse, yet affords health care providers the ability to select the service provider that meets their unique needs.

However, there may be smaller scale projects that are not well suited to the intricacies and nuances of a Request for Proposals (RFP) process. Rather than adopting a prescriptive method of selecting broadband service providers, Colorado suggests a more flexible approach based on the scope and scale of the proposed project; adopting a “small project” waiver to the competitive bid requirements. We are aware that a number of rural HCPS may not have the resources to conduct a formal RFP process and may not participate for that and administrative burden reasons. A second important point is that the Pilot program is different from the HCF program which provides access from and between HCPs (point to point). It does not contemplate services flowing from an HCP’s facility to many points (patients’ homes, etc.) who may currently receive Internet services from different Internet providers.

64. 48. Colorado agrees with the Commission’s proposed language that HCPs should select their service provider and not be restricted to purchasing broadband service from only Eligible Telecommunications Carriers. (ETCs). HCPs should use the competitive bidding requirements contained in the HCF rules (unless exempted due to scope and smaller scale) to solicit bids from as many service providers as are available in the area. This encourages market forces to work and provides the most cost-effective rates for the services requested. The broadband connectivity landscape has dramatically changed in the past several years, affording HCPs with

³¹ See 47 CFR § 54.642(c).

more service provider options. It is generally known that cable companies and rural electric cooperatives are investing in the infrastructure in their communities--connecting homes, businesses and community anchor institutions, such as healthcare providers, with broadband connections capable of 100 Mbps, Gigabit and multigigabit solutions at much lower prices.

If the HCP is limited to ETCs, market forces, where available, will not be leveraged to reduce costs and increase bandwidth. Competitive broadband providers operating in the HCP serving areas would be precluded from competitively bidding on potentially one of the largest businesses in the communities (anchor institutions) and this alone would deter competition which runs counter to encouraging market forces. Some may argue that because ETCs are directly regulated by the FCC, the FCC has more control of an ETC. However, the FCC has already recognized that other service providers, such as rural co-ops, are appropriate carriers and doing so for the Pilot does not change FCC policy nor the ability of the FCC to take regulatory action such as claw-backs.

Limiting the Pilot program to only ETCs would relegate HCP choice to single source contracts, whereby only a limited number of providers could compete for this valuable business. Furthermore, limiting the Pilot to ETCs is antithetical to encouraging competition and innovation and by its limiting nature will preclude the advancement of cost-effective solutions from which the FCC could draw conclusions regarding connected care Pilots. Limiting the participation in the connected care Pilot will only serve to limit the universe of the Pilots proposed and will not provide the FCC with the most robust and innovative solutions possible.

69. In terms of having carrier information available to the public, the FCC's actions in recent years to promote the free flow of information, including the types of Internet and Broadband service offerings and rates has resulted in a better educated public. Much of the information on services and prices can be obtained on-line. ETCs can be required to make that information available. Asking non-ETCs to indicate their desire to provide Internet service would be in their best business interest and the State believes the FCC would see more competition and lower rates as a result.

VI. The FCC should not engage in cost allocation--Internet access provides secondary health benefits of reducing isolation; lessening mental health concerns; and an opportunity to promote integration with Social Determinants of Health and connected care.

In terms of capping patient charges, if you have a single Internet carrier providing service to both the HCP and all of the HCP's participating patients, a reasonable option may be to have the service carrier (or Remote Monitoring Devices company) bill the HCP for both the HCP and the patient's share. If the non-discounted HCP rate was \$100 per month, the HCP would be responsible for paying \$15 a month. If the patient's non-discounted rate was \$40 a month, the patient's share would be \$6 a month. The HCP would be responsible for paying the HCP non-discounted share from eligible sources. This is a consistent theme throughout the FCC's HCF programs. In terms of capping the amount that the HCP can require the patient to pay, the cap would be \$6. It seems appropriate that the HCP could count the patient payment of \$6 as an eligible non-discounted share of the total \$21 cost.³²

34. Colorado is strongly opposed to having a cost allocation for patients who use their Internet access for purposes other than receiving the telehealth services. As stated above, the Promoting Interoperability Program has been very successful in getting Electronic Health Records to health care providers. The HCF has successfully connected HCPs to each other with discounted rates and services. The next logical step is for patients to have Internet access to receive connected care services and converse with their HCPs. What good is it to provide Internet service to the HCP if the patient does not have Internet access?

Adopting a cost allocation methodology would be a disaster to administer. More important, a subsidy for low-income consumers who get a secondary benefit from the Internet connection is a beneficial outcome. Access provides secondary health benefits of reducing isolation; lessening

³² See 47 CFR § 54.633(b)(1): "Eligible sources include the applicant or eligible health care provider participants; state grants, funding or appropriations; federal funding, grants, loans or appropriations except for other federal universal service funding; Tribal government funding; and other grant funding, including private grants."; 47 CFR § 54.633(b)(2) "Ineligible sources include (but are not limited to) in-kind or implied contributions from health care providers; direct payments from vendors or other service providers, including contractors and consultants to such entities; and for-profit entities."

mental health concerns; and an opportunity to promote integration with Social Determinants of Health thus promoting whole-person connect care. It also likely will increase take rates and higher tiered services which ultimately reduce costs for broadband expansion in rural areas.³³

VII. The FCC should simplify the connected care process as much as possible and make it fully electronic to reduce administrative burdens.

103. 67. 70. 40. Colorado understands the rationale for the FCC proposing to mirror many of the administrative processes and forms used for the HCF program. For those HCPs that participate in the HCF program, the processes and Forms 460 and 461 will be familiar. For HCPs that do not already participate in the HCF program (and it is likely that there will be many potential applicants that fall into that category), the HCF process may be quite daunting and may make potential applicants think twice about participating in the Pilot particularly because the rule proposes not to cover administrative costs. For that reason, any modifications to the forms or the Universal Service Access Company (USAC) process to reduce administrative burdens would be helpful.

The existing Form 460 is based on Internet services being provided at “eligible locations.” If Form 460 is used for the Pilot it needs to be revised (perhaps with a check box) to indicate that a patient’s location is deemed an “eligible location.”

All HCPs should be listed on Form 460, block 5. The State recommends that the FCC should encourage innovative telehealth solutions which may involve different types of healthcare and other professionals. Accordingly, Form 460 block 5 should be modified to accommodate this situation. For Form 461, we recommend adding a checkbox to indicate that the project is part of the Pilot program to differentiate it from the HCF Program.

Colorado also recommends that the entire connected care process be made electronic so that the process, like the E-Rate, can be streamlined for more efficient applications, reviews, and reimbursement.

³³ On a similar note, Colorado agrees with the FCC assessment that the Pilot Program will not financially burden existing RHC programs for the same reasons as indicated in this paragraph. Notice of Proposed Rulemaking, WC Docket No. 18-213, Promoting Telehealth for Low-Income Consumers, at para. 29.

Many of the participants in the HCF consist of consortiums comprised of a number of HCPs, due in part to the administrative requirements of the HCF program. Should the FCC adopt some of the HCF administrative requirements for the Pilot program, given that one of the goals of the Pilot is to reduce costs, it would seem as if the FCC would encourage consortiums. Individual HCPs deliver health care services and may not be best suited for issuing RFPs and administration of a Pilot program (especially if the program does not continue after the Pilot phase.)

67. For consortiums, a Letter of Agency seems reasonable. Under the HCF Program, the Letter of Agency consists of all participants. The Pilot Program is different in that most of the “participants” will be patients. While some of the patients may be part of the project for the duration of the project, some may enter or leave the project. The Letter of Agency should consist of the HCPs but not the patients. For that reason, the HCF forms will need to be modified to not require patient participants to sign a Letter of Agency.

Regardless of the definition the FCC uses for HCP, the rule should ensure that the administrative entity can be an entity other than an HCP for consortiums. It is also reasonable that the entity that provides the Letter of Agency be allowed to be the “administrative body” for the consortium. For example, HCPs may participate in a State’s (or regional) Health Information Exchange, or Tribe, which may be the entity best suited to administratively operate the program on the behest of the HCPs. Given that a stated intent of the Pilot program is to establish greater collaboration with CMS, and the fact that state Medicaid agencies are the hub of low-income health care services in a state, the rule should not foreclose a Pilot being submitted by a State (Medicaid, Telehealth, or Broadband Agency) on behalf of HCPs. Similarly, the final rule should affirmatively state that recognized tribes be allowed to submit a Pilot project application.

If the FCC chooses to use the existing forms, consortiums should be encouraged, including those that consist of collaborative efforts between state Medicaid agencies, HCPs, and joint efforts with the VA or tribes. For example, the Notice asks whether applications that include five or more HRSA Health Professional Shortage Areas or HRSA Medically Underserved Areas (MUAs) should be given extra points. If the FCC is going to award extra points for certain types

of projects, we believe that applications that include consortiums and/or collaborative efforts with new and existing CMS or VA demonstration or waivers, or multi-state projects should be awarded extra points.

70. The Notice asks whether a potential applicant should be required to submit a contract for Internet services with the application, similar to the HCF program. While the State appreciates that optimally a contract would accompany the application the Pilot program is different from the HCF program in that the application process itself is competitive. This means that an applicant would have to conduct an RFP process and choose an Internet service provider or remote monitoring device company, not knowing if the application will be awarded a grant. There could be a significant amount of time and energy devoted to the RFP process that may be for naught, and very detrimental to individual HCPs who are already stretched for resources.

53. In terms of establishing a 120 day deadline to submit applications, if the FCC determines that the contract for Internet services must accompany the applications, the 120 days would not be sufficient to develop and submit an application. The HCP would be required to draft, publish, evaluate and choose a vendor, and then negotiate a contract. The 120 days may be sufficient, however, if the application did not have to include an executed contract; it would only need to have an executed contract by the commencement of the project.

50. The State generally agrees with the list of information and documentation that the FCC would require applications to include. As stated above, we do not believe that formal clinical trials are necessary.

The nature of the Pilot does not always lend itself to identifying the exact number of eligible low-income patients. A better gauge would be for the application to identify a range of the number of patients that may receive services under the Pilot.

The FCC proposes to have applicants provide a break-down of the total estimated costs, estimated total ineligible costs, and anticipated sources of financial support. The State appreciates that the FCC uses the term “estimated” costs as the Pilot projects are not like the HCF Program where “costs” are fixed for a period of time by the contract between the Internet service provider and the HCF participants.

93. Colorado believes that self-certification along with random or targeted audits are sufficient to guard against fraud, waste, and abuse. As a condition of each section 1115(a) demonstration approval, the Special Terms and Conditions require that state officials attest to the accuracy of the data provided to CMS, including the data supplied by the HCP. CMS also performs adjudication for every demonstration at the conclusion of each approval period.³⁴ This method has proven to be very effective at avoiding fraud, waste and abuse and a self-certification method would serve the FCC well for the Pilot projects.

71. 74. 75. 76. In terms of Pilot administration, Colorado generally agrees with the timeframes for funding and reimbursement requests. Since many of the Pilots may involve small and rural HCPs and Internet providers, the expectation is that USAC will review and approve reimbursement requests in an expedited and timely manner. Small rural Internet providers cannot afford to wait significant periods of time for reimbursement.

76. To help ensure against fraud, waste, and abuse, Colorado agrees that Pilot projects be subject to random compliance audits by USAC similar to the HCF program. Getting federal funds for projects brings with it the responsibility of participant accountability.

VIII. The FCC should include CMS/ONC on the evaluation team due to their expertise on health programs for low-income and rural patients.

54. The Notice seeks comments on the make-up of the evaluation team. Colorado agrees that FCC officials should participate in the evaluation of proposals. We believe, as suggested by the Notice that involving federal Telehealth Resource Centers would benefit the evaluation process given their expertise in telehealth services. The Notice also seeks comments on how to best collaborate with CMS and ONC to help the HCF improve telehealth. The Notice correctly points out that rate reimbursement is a barrier to telehealth as under traditional payment schemes generally only one HCP can be reimbursed for a particular service. This means that when an HCP refers a patient for say, telehealth services from a psychiatrist, potentially only one of the HCPs is reimbursed. This may result in a disincentive to provide telehealth services.

³⁴ SMD # 18-009 RE: Budget Neutrality Policies for Section 1115(a) Medicaid Demonstration Projects August 22, 2018 State Medicaid Director letter.

Given the Pilot's goals to reduce costs, improve healthcare outcomes, and increase the HCF's contribution to telehealth, the FCC would be wisely served by including CMS and ONC officials on the evaluation team. The foundation of the Pilot is health care services and these federal agencies are integral to the reimbursement scheme for the health care services to be performed under the Pilot. Colorado strongly encourages including CMS and ONC officials on the evaluation team. Similarly, the Pilot evaluation could be better served by having VA and tribal representatives participate in the evaluation process.

The FCC would be best served by collaborating with CMS/ONC to identify mutual goals and strategies and adopt outcome-based reporting and evaluation mechanisms.

75.97.98. Throughout our comments, Colorado has expressed a theme of flexibility and outcome-based approaches for the Pilot projects based in part, on the size, scope, and type of Pilot project. Generally speaking, the rule should include data fields such as the number of patients per month; specific health conditions treated; types of connected care services for each condition; average frequency of patient use of each type of connected care service; health outcomes for patients; and average cost-savings per patient. Since a purpose of Pilot is to collect data and test the efficacy of connected USF support mechanism, the Notice asks for the best methods to ensure HCPs are regularly reporting useful and required data and tying that requirement to reimbursement. Colorado believes that if the Pilot project does not meet these requirements, the Pilot project could be required to enter into a remedial action plan to bring the project into compliance. If that does not happen, the FCC would be well within its jurisdiction to retain funds until the project is in compliance.

It is likely that the total number of patients may vary depending on the services provided and the health condition (e.g., pregnancy). The report should include a rolling inventory of the number of patients along with the health conditions treated.

75. The Notice seeks comments on requiring HCPs to submit raw data. The administrative burdens of submitting raw health data on study participants to determine the effects of the treatment likely outweigh and benefit of having raw data. What would be the purpose of having the raw data? Who at the FCC or related agencies would analyze the data? HIPAA allows

de-identified data to be shared. If raw data are submitted there could be HIPAA concerns that left unresolved could diminish the Pilot's worth.

The intent of the rule is to measure the resulting improvement in the efficiency and effectiveness of telehealth at the Project level. Of course, the HCP and the patient would have established expectations and measure the individual health outcomes, but the measurement of the success of the whole Pilot project, is at the higher project level. Any concerns about the accuracy of the information provided can be dealt with through the use of targeted or random reviews and audits.

Every state, under the CMS Promoting Interoperability Program is required to have an approved State Medicaid Health Plan (SMHP) which is a detailed five-year roadmap of Health Information Technology in the state, including telehealth services. The SMHP includes mission, goals, objectives, milestones, activities, and measurements along with deliverables and tracking. For Pilot projects that propose a collaborative approach with Medicaid, the VA, or other entities within the state, requiring the applicant to submit current state Health Information Technology roadmaps would provide the FCC with even more assurances of program integrity, including measurement of improved health outcomes resulting from the proposed telehealth project. Colorado recommends the FCC work jointly with CMS/ONC to identify mutual goals and outcomes. For applications that involve CMS/ONC projects, the FCC could require Pilot projects to submit CMS approval letters and reports to ensure that the Pilot meets both FCC and CMS requirements and to guard against fraud, waste, and abuse.

CONCLUSION

Colorado once again thanks the FCC for the opportunity to provide comments on this exciting new Pilot to link Internet access with remote and telehealth services and improve health outcomes for low-income rural patients. We believe that the FCC has the legal authority to create a Pilot project and want to reiterate our support of the Pilot. We further encourage the FCC to adopt an outcome-based approach for the Pilot project recognizing the evolving definition of health and health professionals, new and existing CMS and VA and tribal initiatives, and its own connected care.