

Before the
FEDERAL COMMUNICATIONS COMMISSION
Washington, DC 20554

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

COMMENTS OF THE AMERICAN HOSPITAL ASSOCIATION

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The American Hospital Association (“AHA”)¹ hereby submits the following comments on the Federal Communications Commission’s (“FCC” or “Commission”) Notice of Proposed Rulemaking (“*NPRM*”) in the above-captioned proceeding.²

I. INTRODUCTION AND SUMMARY.

In its comments and reply comments on the Notice of Inquiry (“*NOI*”) for this proceeding,³ the AHA endorsed the Commission’s proposed Connected Care Pilot program (“Pilot Program” or “Program”) and the Commission’s focus on promoting delivery of health care directly to a patient’s home or mobile location via a broadband Internet connection (“connected care”).⁴ The AHA agrees that the Pilot Program will serve multiple purposes: in

¹ The AHA is a national organization whose membership includes nearly 5,000 member hospitals, health systems, and other health care entities; clinician partners (including more than 270,000 affiliated physicians, two million nurses and other caregivers); and 43,000 individual members. Through its representation and advocacy activities, the AHA ensures that member perspectives and needs are heard and addressed in national health policy development, legislative and regulatory debates, and judicial matters. In addition, the AHA provides education for health care leaders and is a source of information on health care issues and trends.

² *Promoting Telehealth for Low-Income Consumers*, Notice of Proposed Rulemaking, WC Docket No. 18-213, FCC 19-64 (rel. July 11, 2019) (“*NPRM*”).

³ *Promoting Telehealth for Low-Income Consumers*, Notice of Inquiry, 33 FCC Rcd 7825 (2018) (“*NOI*”).

⁴ See generally Comments of The American Hospital Association, WC Docket No. 18-213 (filed Sept. 10, 2018) (“AHA NOI Comments”); Reply Comments of The American Hospital Association, WC Docket No. 18-213 (filed Oct. 10, 2018) (“AHA NOI Reply Comments”).

addition to providing near-term funding to support connected care services (particularly for low-income consumers and veterans), it will supply the Commission with data on the types of connected care services that are most effective. The Program will also provide some insight into how future universal service funding and other regulatory reforms might best expand the availability of those services throughout the country.⁵

Certainly, the *NPRM* is timely. Connected care is a form of telehealth, and it is well documented that telehealth can provide patients with the right care, at the right place, at the right time, and at lower cost. And, use of telehealth in hospitals and among physicians is growing steadily. Nonetheless, there remain substantial barriers to widespread adoption of connected care (and telehealth generally), including, among other things, reimbursement issues, cross-state licensing, credentialing and privileging laws, and, perhaps most important, lack of patient access to affordable end-user devices and broadband connections capable of supporting connected care services, especially in rural areas. To the extent it addresses the latter problem, the Pilot Program is a welcome and critical step towards advancing the progress of connected care. The AHA, thus, urges the Commission to adopt rules that will implement the Pilot Program as soon as possible.

The AHA believes that the Pilot Program must be grounded in the following core principles in order to be successful: (1) the Program's rules should maximize eligibility to ensure a truly diverse applicant pool, while establishing at least a partial preference for health care providers ("HCPs") that serve rural communities; (2) the Commission must acknowledge that hospitals and other HCPs already spend billions of dollars on regulatory compliance, and

AHA incorporates the AHA NOI Comments and AHA NOI Reply Comments herein by reference and asks that they be included in the record for the *NPRM*.

⁵ See *NPRM*, ¶¶ 1-2.

therefore should streamline the Program’s application process, post-application reporting requirements, and performance evaluation metrics to minimize any additional administrative burdens; and (3) the Commission must recognize that an HCP’s launch and operation of a connected care pilot will entail substantial costs, and the Commission thus should take an expansive view of what costs will be eligible for funding under the Program. Consistent with these principles, and as discussed in greater detail below, the AHA recommends that the Commission take a variety of steps, including but not limited to the following:

- expand Program eligibility to include both urban and rural HCPs, and for-profit hospitals;
- provide applicants with sufficient latitude to design their connected care proposals in a manner best suited to their patients;
- simplify application forms and ensure that they include very clear directions and specific guidance as to what uses of Program funding will be permissible;
- dedicate sufficient staff to providing technical and other assistance to HCPs that may be new to the funding process or do not have adequate resources to complete applications entirely on their own;
- when awarding “extra points” among competing proposals, use a less restrictive definition of “rural” and recognize the work applicants are doing to study and cure medical conditions not specifically addressed in the *NPRM*;
- allow Program participants to report data on an aggregated basis;
- limit any data reporting requirements to annual reporting, without mandating that Program participants conduct clinical trials;
- adopt simple and realistic metrics for measuring a project’s success;
- make funding available for, at a minimum, administrative expenses, internal connections, network equipment, end-user devices, medical devices and mobile applications;
- retain flexibility to fund approved projects in varying amounts; and
- at the election of HCPs, provide reimbursements directly to service providers.

II. THE PILOT PROGRAM WILL FACILITATE ADOPTION AND FUNDING OF CONNECTED CARE SERVICES.

To be sure, telehealth is growing steadily in the United States. For example, the percentage of hospitals fully or partially implementing a computerized telehealth system grew from 35% in 2010 to 76% in 2017.⁶ According to American Well’s 2019 Physician Survey, physician telehealth adoption is up 340% since 2015; physician willingness to use telehealth is up to 69% versus 57% in 2015.⁷ And the benefits of telehealth are well-established – the proof lies in the successful telehealth programs launched by HCPs across the country. To cite just a few:

Project ECHO (Extension for Community Healthcare Outcomes): Project ECHO, based in New Mexico, dramatically increases access to specialty treatment in rural and underserved areas by providing front-line clinicians with the knowledge and support they need to manage patients with complex medical conditions. It does this by engaging clinicians in a continuous learning system and partnering them with specialist mentors at an academic medical center or hub. As the ECHO model expands, it is helping to address some of the health care system’s most intractable problems, including inadequate or disparities in access to care, rising costs, systemic inefficiencies, and unequal or slow diffusion of best practices.⁸

Illinois Telehealth Network: The Illinois Telehealth Network (“ITN”) is a member-based, voluntary network of independent organizations working together to address widespread

⁶ American Hospital Association, “Fact Sheet: Telehealth” (February 2019), <https://www.aha.org/factsheet/telehealth>.

⁷ American Well, “Telehealth Index: 2019 Physician Survey,” at 1, 4, <https://static.americanwell.com/app/uploads/2019/04/American-Well-Telehealth-Index-2019-Physician-Survey.pdf> (“American Well Study”).

⁸ See <https://echo.unm.edu/about-echo>.

medical provider and care shortages in rural, underserved and disadvantaged areas in Illinois. It currently consists of 26 members collaborating to help eliminate barriers to health care access. The ITN provides support to its network members through training, resource sharing, technical support, collaborative grant efforts, networking and sharing economies of scale for purchasing.⁹

Avera eCARE Pharmacy: Since 2009, eCARE Pharmacy has provided remote, around-the-clock pharmacy coverage for more than one million patients across 95 sites. No matter the size or location of a facility, a hospital can ensure medication safety for patients 24 hours a day by partnering with eCARE Pharmacy. Hospitals gain access to licensed and clinically-trained pharmacists for real-time, first dose order reviews and instant consultations on medication-related issues or concerns. The eCARE Pharmacy team works together in a virtual hospital hub and collaborates with a customer hospital's pharmacy and/or professional staff to assist with complex situations, while ensuring that patients receive the most effective medications.

Banner Health Ambulatory Care Program: Based in Phoenix, Arizona, Banner embraced telehealth with the launch of its tele-ICU system more than a decade ago. More recently, to better manage its chronically ill population, Banner launched its Intensive Ambulatory Care (“IAC”) telehealth program. Patients were provided with remote patient monitoring tools – such as scales, glucometers and heart monitors – that were Bluetooth-enabled, along with a tablet for video visits. According to analysis of patient results over the first full year of the program, overall costs of care were reduced by 34.5%; hospitalizations were reduced by 49.5%; the length of hospital stays was reduced by 50%; and the 30-day readmission rate was reduced by 75%.

⁹ See <https://www.illinoistelehealthnetwork.org>.

Intermountain Healthcare: Intermountain has launched more than 35 telehealth initiatives in Utah, Idaho, Wyoming, Nevada and Montana. One of the system-wide initiatives focuses on newborn intensive care: 18 rural hospitals, including two non-Intermountain facilities, now have access to Intermountain neonatologists through telehealth. Another major initiative, focusing on stroke diagnosis in 21 emergency departments, underscores the importance of speedy access to specialists. Telehealth makes a neurologist rapidly available to assess the situation, respond and deliver the required care; more than 1,000 patients have benefited from the telestroke program so far. Another system-wide initiative addresses behavioral health, specifically crisis care support – the program makes a social worker available faster than would normally be the case for patients in rural facilities. More than 1,000 patients have been treated through the behavioral health program.¹⁰

In addition, telehealth allows physicians to use flexible work schedules, achieve a better work/life balance and spend more time with each patient, thereby reducing physician burnout.¹¹ Further, telehealth can be an effective tool for, among other things, crisis intervention¹² and

¹⁰ For more information about the telehealth programs discussed above and others, see American Hospital Association, “Telehealth: Delivering the Right Care, at the Right Place, at the Right Time” (July 2017), <https://www.aha.org/system/files/content/17/telehealth-case-examples.pdf>.

¹¹ See, e.g., American Well Study at 6.

¹² Remote consultations and evaluations remove the need to relocate a patient in crisis, and can de-escalate crisis situations without potentially dangerous face-to-face interactions.

psychiatric care of children, adolescents,¹³ and patients in long-term care facilities such as nursing homes.¹⁴

Nonetheless, “many health care providers and patients have not yet adopted connected care services.”¹⁵ There are a number of reasons for this. Medicare, for instance, imposes geographic limitations on where telehealth services will be covered, and in any case only provides coverage of a small, defined set of services.¹⁶ State licensure laws can be major obstacles for facilities that want to provide telehealth services to patients in other states.¹⁷ Credentialing and privileging requirements also may be problematic because telehealth services usually involve multiple health care facilities that must each credential and privilege the practitioner(s) providing care.¹⁸ Concerns about other state regulations, privacy, security and fraud and abuse are among the other reasons why telehealth adoption has not progressed at a

¹³ While there is less data on the feasibility of telepsychiatry with child and adolescent patients, the evidence on this subject has increased considerably over the past decade. In particular, short-term telepsychiatry intervention for ADHD achieved success versus ongoing primary care management.

¹⁴ Especially in areas without sufficient psychiatric coverage, long-term care facilities can contract with telepsychiatry providers to offer regular assessments and cognitive interventions.

¹⁵ *NPRM*, ¶ 12.

¹⁶ *See, e.g.*, Letter from Thomas P. Nickels, Executive Vice President, American Health Association, to Congressional Telehealth Caucus, at 6 (April 2, 2019), <https://www.aha.org/system/files/media/file/2019/04/web-AHALettertoTelehealthCaucus-Senate-040219.pdf>. As of calendar year 2019, only 98 individual service codes out of more than 10,000 physician services covered through the Medicare Physician Fee Schedule are approved for payment when delivered via telehealth. *Id.*

¹⁷ *Id.* at 7.

¹⁸ *Id.* at 8.

faster pace.¹⁹ And, of course, lack of access to affordable, robust broadband connections is a persistent problem, particularly in rural areas.

To be sure, progress is being made on some of these fronts.²⁰ But, as the Commission points out, save for the U.S. Department of Veteran Affairs' Home Telehealth Program, "no federal agency currently offers funding to health care providers for use for patient connectivity in connected care."²¹ The AHA, thus, continues to support an expeditious launch of the Pilot Program and concurs that universal service funding can and should be explored as a means of addressing the connectivity problem. If successful, the Pilot Program should lay the groundwork for future funding of connected care on a more permanent basis.

¹⁹ *Id.*

²⁰ For example, Section 1834(m) of the Social Security Act contains a list of the Medicare telehealth codes covered under Medicare's Physician Fee Schedule ("PFS"). Last year, the Centers for Medicare & Medicaid Services ("CMS") established separate payment for communication technology-based "check-ins" and remote evaluation of patients' pre-recorded images or videos (meaning that these services would not be subject to the same restrictions associated with other telehealth services listed in Section 1834(m)). In addition, several alternative payment models ("APMs") waive the geographic, siting and other restrictions on telehealth imposed by Medicare, thus giving APM participants more freedom to offer telehealth services. And, CMS recently finalized its plan to expand telehealth access and coverage in Medicare Advantage ("MA") plans. CMS's new rules eliminate geographical restrictions on telehealth access and telemedicine services in MA plans by 2020, enabling those in urban areas to use connected health technology. The new rules will also give MA members more locations from which to access care, including their own homes. See Wicklund, "CMS Finalizes Telehealth Expansion for Medicare Advantage Plans," *mHealth Intelligence* (April 8, 2019), <https://mhealthintelligence.com/news/cms-finalizes-telehealth-expansion-for-medicare-advantage-plans>.

²¹ *NPRM*, ¶ 13.

III. THE COMMISSION’S RULES FOR THE PILOT PROGRAM SHOULD MAXIMIZE ELIGIBILITY AND MINIMIZE ADMINISTRATIVE BURDENS ON PROGRAM PARTICIPANTS.

A. ELIGIBILITY

To enhance the Pilot Program’s prospects for success, the Commission should encourage participation by a diverse pool of applicants without limitations on applicant size or geographic location. This is a pilot program, whose main purpose should be to gather data about programs that work. Diversifying the applicant pool will help achieve this objective. The AHA, thus, supports the Commission’s proposal to open eligibility to both urban and rural HCPs, all of which serve low-income patients who are the intended beneficiaries of the Program.²² Furthermore, the Commission’s eligibility criteria should not exclude for-profit hospitals, which also serve low-income patients and play a critical role in delivering health care to underserved areas. As such, their participation would help achieve the goals of the Program as described in the *NOI*.²³

To further encourage diversity in the applicant pool, the Commission should give HCPs sufficient flexibility to focus their proposals on specific health conditions and geographic areas that they believe are in greatest need of connected care solutions. Funding, in other words,

²² *Id.*, ¶ 42.

²³ See *NOI*, 33 FCC Rcd at 7832-34 (identifying Pilot Program goals as improving health outcomes through broadband access; supporting the trend towards connected care everywhere; reducing health care costs for patients, facilities, and the health care system; determining how universal service funding can positively impact existing telehealth initiatives; increasing broadband deployment in unserved and underserved areas; and increasing adoption of broadband in low-income households). The AHA does not believe there is anything in Section 254(h)(7)(B) of the Communications Act which precludes the Commission from treating for-profit hospitals as “health care providers” for the limited purposes of a temporary pilot program. If the Commission believes otherwise, the AHA would support an amendment to Section 254 to permit for-profit hospital participation in the Pilot Program.

should not be limited to narrow categories of projects. Likewise, the Commission should permit applicants to use whatever equipment and end-user devices are most compatible with their proposed technical design. It is also unnecessary and counterproductive to limit participation to HCPs that are federally designated as Telehealth Resource Centers or Telehealth COEs, as these entities do not comprise the entire universe of HCPs that need connected care funding.²⁴

The Commission asks how it can ensure that participating HCPs have significant experience with providing long-term patient care.²⁵ By way of example, hospitals and clinics have substantial experience with comprehensive long-term care and should be viewed as such during the application process. To the extent the Commission is concerned about the experience level of Program participants, it should encourage community-focused connected care proposals. Projects driven by local communities that bring together HCPs in partnership with broadband providers, telehealth service/application providers, and community leaders are more likely to attract experienced HCPs and should be preferred over projects from a single HCP or company that has limited reach.²⁶

B. THE APPLICATION PROCESS

Many HCPs have only limited resources for assessing the broadband needs of their patients and designing, drafting, filing and monitoring grant proposals. They, therefore, are less likely to participate in the Pilot Program if the FCC's application process is unduly complex or restrictive. This is especially the case for small and rural HCPs.

²⁴ *NPRM*, ¶ 45.

²⁵ *Id.*, ¶ 44.

²⁶ Similarly, the Commission's rules also should permit HCPs to partner with social service providers.

Accordingly, to minimize the administrative burdens on potential HCP applicants (and thereby maximize participation in the Pilot Program), the Commission should design its application process as follows:

- Any pre-application registration process should be minimal and easy to navigate. Registrations should have either no expiration date or otherwise remain valid for a long period of time, so as to not prevent or delay an HCP's application.
- Parameters of Pilot Program funding should be made transparent and communicated clearly in order for applicants to understand how Program funds can and cannot be utilized, and how the funds will be administered. This will help ensure that HCPs develop realistic applications that are not rejected on technicalities.
- Program applications should have very clear instructions and solicit only that amount of information that is essential for evaluating applicant qualifications. This is necessary to accommodate smaller and rural HCPs that may not be familiar with the process of obtaining federal grants and/or do not have grant-writing staff or other personnel devoted to obtaining grants. Application instructions should specify what if any data substitutes will be permitted, in the event that an applicant does not have the preferred information but does have a suitable alternative. If the Pilot Program has specific geographic or other targets for funding, they should be made clear to applicants so that they can properly evaluate whether their proposals are likely to be successful. The FCC must also be clear on how applicants will be permitted to engage patients to participate in proposed projects.
- Applicants should be advised (preferably in the instructions to the application form) as to the estimated time frame for processing of their applications, who will be reviewing their applications, and how they can obtain updates on the status of their applications.
- Sufficient Commission and/or USAC staff should be dedicated to providing technical and other assistance to HCPs during application preparation. Samples or templates of what a completed, acceptable application should look like would be helpful.
- The Commission's proposed 120-day application window is not unreasonable.²⁷ History has shown, however, that some HCPs do not learn about grant opportunities when they first become available (since they do not have full-time employees devoted to searching for those opportunities). Thus, once rules are adopted, the Commission might consider alternative ways of publicizing its application window for the benefit of those HCPs that do not have the resources to proactively search for grants (*e.g.*, publishing a "reminder" public notice no less than 30 days prior to the application window, coordinating with federal and state health care agencies to ensure that any FCC public notices relating to the application window are published on their websites). Moreover, to the extent that the Commission's rules encourage HCPs to form consortia or partnerships with other entities,

²⁷ *NPRM*, ¶ 53.

the AHA would not be opposed to extending the window for an additional 30 days to ensure that HCPs have sufficient time to negotiate those arrangements.

C. APPLICATION EVALUATION AND AWARDING OF EXTRA POINTS

As an initial matter, the Commission should keep the “resources gap” in mind when comparing the proposals of smaller HCPs to those of larger HCPs. Due to differences in grant-writing capacity, such comparisons could unintentionally disadvantage smaller HCPs whose proposals otherwise merit funding. The AHA, therefore, asks that the Commission consider “peer-grouping” applications so that HCPs with similar characteristics are properly reviewed against each other.

The AHA supports the Commission’s proposal to award extra points where, *inter alia*, an HCP is located in a rural area or would primarily serve patients who reside in rural areas.²⁸ By the same token, the AHA believes that the existing definition of “rural area” in the Commission’s Rural Health Care program rules is not sufficiently inclusive. Under Section 54.600(b) (47 C.F.R. § 54.600(b)), a rural area “is an area that is entirely outside of a Core Based Statistical Area; is within a Core Based Statistical Area that does not have any Urban Area with a population of 25,000 or greater; or is in a Core Based Statistical Area that contains an Urban Area with a population of 25,000 or greater, but is within a specific Census tract that itself does not contain any part of Place or Urban Area with a population of greater than 25,000.”²⁹ As a result of the 2010 Census and the most recent nationwide CBSA designations, some areas that were previously considered rural are now deemed non-rural, irrespective of whether the affected populations have gained better access to health resources.

²⁸ *Id.*, ¶ 57.

²⁹ *Id.* n. 128, quoting 47 C.F.R. § 54.600(b).

Other federal agencies, such as the Health Resources & Service Administration’s Federal Office of Rural Health Policy (“FORHP”), have adopted alternative definitions of rural that may be more inclusive and equitable.³⁰ The AHA, therefore, urges the Commission to recognize shortcomings of the current definition, and adopt an alternative approach that would be more inclusive, equitable and consistent with the Pilot Program’s objectives. A key goal of the Program should be to support HCPs that are in and/or serve persons that reside in rural areas, notwithstanding their status according to the Census.

The AHA also supports the Commission’s proposal to award additional points to projects focused on treating “certain chronic health conditions or conditions that are considered health crises, such as opioid dependency, high-risk pregnancies, heart disease, diabetes, or mental health conditions.”³¹ The Commission should not, however, limit the health conditions that may be eligible for extra points under the Pilot Program. Many HCPs are doing good work in developing methods of treatment for conditions that, while perhaps not “chronic” in the strict sense, may nonetheless raise serious health concerns in their respective service areas (*e.g.*, stroke-prevention) and thus merit special consideration under the Program.

D. DATA GATHERING AND REPORTING

In principle, the AHA does not disagree that the Pilot Program should include a data gathering and reporting requirement to measure whether the Program is achieving its goals by

³⁰ For example, FORHP accepts all non-Metro counties as rural and uses an additional method of determining rurality called the Rural-Urban Commuting Area (“RUCA”) codes. Like Metropolitan Statistical Areas (“MSAs”), these are based on Census data that is used to assign a code to each Census Tract. Tracts inside Metropolitan counties with the codes 4-10 are considered rural. See <https://www.hrsa.gov/rural-health/about-us/definition/index.html>.

³¹ *NPRM*, ¶ 61.

permitting evaluation of connected care’s impact on health care outcomes.³² But, those requirements must achieve the proper balance between the value of the information and the additional regulatory burden that data collection and reporting will impose on HCPs that participate in the Program. HCPs are already highly regulated and spend billions on regulatory compliance. According to a study published by the AHA, an average-sized community hospital (161 beds) spends nearly \$7.6 million annually to support compliance with federal regulations from just four agencies.³³ That figure rises to \$9 million for hospitals with post-acute care beds. Nationally, this equates to \$38.6 billion each year.³⁴ Viewed another way, regulatory compliance costs \$1,200 every time a patient is admitted to a hospital.³⁵ Any data gathering and reporting obligations under the Program must be viewed against this backdrop.

The AHA, thus, agrees that participating HCPs should only be required to submit anonymized, aggregated data, or masked data if submission of anonymized data is not possible due to an extremely small number of patient participants (such that they could be readily identified).³⁶ HCPs should not, however, be required to submit such data more than once a year,

³² *Id.*, ¶ 94.

³³ American Hospital Association, “Regulatory Overload: Assessing the Regulatory Burden on Health Systems, Hospitals and Post-acute Care Providers,” at 4 (Oct. 2017), <https://www.aha.org/system/files/2018-02/regulatory-overload-report.pdf>. Those agencies are CMS, the Office of Inspector General, the Office for Civil Rights and the Office of the National Coordinator for Health Information Technology. *Id.* at 1.

³⁴ *Id.* at 4.

³⁵ *Id.* Moreover, the administrative burdens of the Rural Health Care Program are already significant and have proven to be the highest barrier to HCP participation.

³⁶ *NPRM*, ¶¶ 95, 101. Patient-level reporting – even on a de-identified basis – introduces a variety of security risks, and it is not clear that the FCC has the infrastructure to accept patient-level data. Compare, for example, CMS, which accepts patient-level data via a secure portal called QualityNet. CMS imposes a variety of requirements on HCPs and individuals before they

as a quarterly or even semi-annual reporting requirement may prove to be excessive for smaller or rural providers that already are committing a sizable portion of their budgets to regulatory compliance and may have very few staff personnel available for reporting activities.³⁷ And, as noted by the Rural Policy Research Institute Health Panel (“RUPRI”), “[r]ural hospitals may require a longer data collection interval to achieve a data volume that returns reliable results.”³⁸ It also takes time for HCPs to ramp up their data collection processes, ensure that their data collection systems are set up to capture the relevant data fields, and package the data properly for reporting. Having an annual data submission deadline will give HCPs sufficient time to implement their data collection processes for the Program without having to worry about complying with that particular quarter’s reporting deadline.

The AHA makes the following additional recommendations on data reporting:

- The FCC should open whatever system it uses to accept data as early as possible. For example, many CMS quality reporting programs start accepting data at least two months before the relevant data submission deadline.³⁹
- The FCC should have a mechanism that enables program participants to confirm that they have submitted their data and that the data has been accepted into the FCC’s data collection system (again, CMS programs have this).

can even be eligible to register for QualityNet (e.g., annual security training, identity verification, rules of acceptable behavior, and attestations).

³⁷ Also, where a smaller or rural HCP partners with a larger HCP in the Program, the FCC should allow the relevant data reports for the partnership to come from the larger HCP, which presumably would have more capacity for reporting activities.

³⁸ Rural Policy Research Institute Health Panel Response to CMS’ *Report to Congress: Plan to Implement a Medicare Hospital Value-Based Purchasing Program*, at 12 (Oct. 2008), http://www.rupri.org/Forms/RUPRI_VBPRResponse.pdf.

³⁹ The FCC can further lighten the reporting burden on smaller or rural providers by focusing only those metrics that are truly relevant to the goals of the Program; creating feasible and user friendly vehicles for reporting data; and making FCC and/or USAC staff available to assist HCPs during the data collection and reporting process.

- The data collection process should include a “review/correction” period during which a Program participant has an opportunity to submit any missing data identified during FCC review. In addition, and particularly for the benefit of HCPs that are not accustomed to submitting information to the FCC, a grace period of 15 to 30 days after the first reporting deadline would be appropriate.
- Should patient surveys be required,⁴⁰ the Commission should develop a very short standard survey (no more than three to five questions) that HCPs could send out during a timeframe of their own choosing). This data too should be reported annually or at the conclusion of the project.

Lastly, the Commission should not require participating HCPs to use clinical trials to measure the effects of connected care on health care outcomes.⁴¹ Even for a large HCP with adequate resources, running clinical trials is a daunting task. Many HCPs, for example, require human subjects research approval through an institutional review board (“IRB”) before a trial may even commence. IRB processes are notoriously slow, and the AHA believes that many (if not most) rural hospitals that might apply to participate in the Program do not have an IRB or any infrastructure for conducting clinical trials.

E. METRICS

It is important that the Pilot Program measure the impact of the remote monitoring interventions it supports.⁴² Given the purpose of the projects authorized under the Program, such measurements will be valuable in identifying changes in behavior, in addition to health outcomes. The AHA submits, however, that the metrics for program measurement should be kept simple and focus on direct rather than indirect outcomes. The complexity of human health can make it very difficult to link a single intervention to outcomes such as mortality or even

⁴⁰ *NPRM*, ¶ 99.

⁴¹ *Id.*, ¶ 96.

⁴² *Id.*, ¶ 89. *See also* AHA *NPRM* Comments at 9.

hospitalizations. Thus, the Program should utilize more specific measurements that are linked directly to the interventions being funded. These could include tracking of patient interactions via remote monitoring and assessments of whether biometrics associated with a given condition are improved. For example, have diabetics been able to manage their blood glucose levels, or have individuals with hypertension achieved better control of their blood pressure? Remote monitoring tools also could be used to collect data on how healthy individuals feel, and whether they feel in control of their health.

In any case, the FCC should allow HCPs to specify in their applications reasonable metrics based on the targeted interventions they plan to undertake, rather than imposing mandatory, “one-size-fits-all” metrics that may not be appropriate for an HCP’s individual circumstances. This is especially necessary for smaller or rural HCPs whose data must be interpreted in the context of lower patient volume (thus rendering certain metrics statistically invalid).

F. FUNDING AND DISBURSEMENT ISSUES

Because the costs of providing broadband access likely will be only a small portion of a connected care project’s overall costs, an HCP, once its application is granted, will have significant Program-related obligations that, if not funded at least in part, may render projects uneconomical.⁴³ Those obligations include, among other things, identifying eligible patients and engaging them to participate in the HCP’s project; ensuring that patients have the appropriate telehealth technology, and teaching them how to link that technology to the HCP; troubleshooting issues patients may experience in using the technology; and retaining a program manager whose responsibilities will include project planning, changing work flows as necessary

⁴³ See AHA NOI Reply Comments at 3-4.

to support the project, contracting, outreach and communications, and technology choice and acquisition.⁴⁴ All of these responsibilities entail substantial start-up and implementation costs which may be especially burdensome for understaffed and/or underfinanced HCPs.

Furthermore, these costs are both short-term and long-term (an example of the latter is the cost of checking end-user device functionality and updating the relevant technology as necessary).

Failure to even partially fund them threatens an HCP's ability to sustain a project for its entire term. HCPs are less likely to participate in the Pilot Program if the Commission does not factor the above-described costs into the funding equation.

The AHA, thus, supports funding of internal connections and network equipment,⁴⁵ and urges the Commission to reconsider its proposal not to fund HCP administrative expenses.⁴⁶ Notably, the Commission does not cite any legal barriers to funding of such expenses. It only states that “past experience in the RHC support programs and RHC Pilot program demonstrates that ‘[health care providers] will participate even without the program funding administrative expenses.’”⁴⁷ Given the size of the financial commitment HCPs must make toward designing and implementing successful proposals under the Pilot Program, the resources required to manage, measure and report on patient participation and health care outcomes, and the technical

⁴⁴ Further, in rural communities where WiFi is not available, there may be a need to maintain data plans for mobile devices. These are ongoing monthly costs in addition to the upfront costs of equipment and service.

⁴⁵ *NPRM*, ¶¶ 23-24. In funding network equipment, the Commission should account for the fact that connectivity, equipment and software are constantly changing, and that the “best” technology today may be superseded by new technology tomorrow. Accordingly, the Program needs to be flexible enough to permit funding of network maintenance (including equipment changeouts) and software upgrades.

⁴⁶ *Id.*, ¶ 25.

⁴⁷ *Id.*

challenges associated with telehealth generally, the Commission can no longer assume that HCPs will participate in the Pilot Program when administrative expenses are not funded. Likewise, the Commission should not assume that HCPs will have alternative sources of outside funding for those expenses (and the Commission should consider the administrative burden on smaller or rural HCPs of having to pursue multiple sources of outside funding for the same project, and thereby having to shift even more of their already sparse resources from operations to grant-related activities).

The Commission likewise relies on past history rather than legal arguments in concluding that the Program will not fund end-user devices, medical devices or mobile applications. While it is true that the Commission has elected not to fund these items in other USF programs, more recently those decisions have been a policy choice, not a legal barrier.⁴⁸ Here, for the purposes of a discrete, time-limited pilot program intended to gather data to create a permanent program, the Commission should exercise its broad discretion under Section 254 to support the funding of end-user devices *et al.*, especially since meaningful adoption of telehealth services by low-income consumers (and, thus, the success of the Connected Care Pilot Program) requires affordable access to end-user equipment.⁴⁹ Note that HCPs have little flexibility to provide such equipment themselves, since anti-kickback statutes prohibit HCPs from giving or receiving giving items of value (such as monitoring equipment), as they could be seen as an inducement. Funding of these costs directly through the Program would, therefore, be particularly beneficial, whether it be for purchasing new devices or updating existing ones.

⁴⁸ See AHA NOI Comments at 10-11 and the cases cited therein.

⁴⁹ See AHA NOI Comments at 4-6 for a discussion of the Commission's legal authority under Section 254.

The AHA supports the Commission’s proposal to devote a total of \$100 million in USF funding to the Pilot Program, its proposal not to expressly limit the number of funded projects, and its proposal to permit flexible and varied funding for each project.⁵⁰ Such flexibility is essential here, since per-project funding must be significant enough to ensure each project’s success. Fewer sufficiently funded projects producing measurable and tangible results will be more useful than numerous underfunded projects that yield less helpful results.

The Commission proposes to issue funding to “defray the costs of purchasing broadband Internet access service necessary for providing connected care services directly to qualifying patients.”⁵¹ The AHA supports this, but urges the Commission to clarify that HCPs are not responsible for establishing such service where it does not already exist. In all cases, the responsibility for constructing and operating a broadband service must rest with the HCP’s service provider.

Finally, the AHA believes the Commission should give participating HCPs the option of having disbursements made directly to their service providers, rather than having the HCPs handle the process.⁵² As shown above, HCPs with limited resources will have substantial responsibilities under the Pilot Program, and should not be in the middle of the disbursement process if they are not equipped for that task. For similar reasons, the Commission should not tie the issuance of disbursements to a project’s compliance with the Program’s data-reporting requirements.⁵³ Withholding disbursements under such circumstances would be of greatest harm

⁵⁰ *NPRM*, ¶¶ 28, 33.

⁵¹ *Id.*, ¶ 17.

⁵² *Id.*, ¶ 74.

⁵³ *Id.*, ¶ 75.

to smaller or rural HCPs that may struggle to meet their reporting obligations but provide essential health care services to their communities. At most, the Commission should tie disbursements only to submission of whatever subset of data it deems most essential to the Program.

IV. CONCLUSION.

The AHA looks forward to working with the Commission as it develops and finalizes its rules for the Connected Care Pilot Program. If there are any questions regarding these comments, please contact me or Shira Hollander, senior associate director of payment policy, at shollander@aha.org.

Respectfully submitted,

By: _____ /s/ _____

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