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Centers for Medicare & Medicaid Services
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Attention: CMS-1744-IFC, Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency

The staffs of the Federal Trade Commission’s (“FTC”) Office of Policy Planning, Bureau of Economics, Bureau of Competition, and Office of the General Counsel¹ (collectively, “FTC staff”) appreciate the opportunity to respond to your request for comments on the Interim Final Rule with Comment Period entitled *Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency* (“IFC”).² The IFC aims to give flexibility, such as an increased ability to use telehealth, to individuals and entities that provide services to Medicare beneficiaries. The IFC therefore may enable these service providers to respond more effectively to the serious public health threats posed by the pandemic.

Public and private reimbursement laws and policies frequently are cited as impeding the development and widespread use of telehealth services. By limiting entry of telehealth practitioners, overly restrictive reimbursement requirements may unnecessarily limit consumers’ access to care and choice of practitioner, especially in areas where there is a shortage of healthcare professionals and at times outside normal business hours. Reducing restrictions on Medicare reimbursement for telehealth services is especially important, not only to enhance the use of telehealth to care for Medicare beneficiaries, but also to encourage private payers to expand the use of telehealth. Reducing or eliminating restrictions on reimbursement of telehealth services could potentially enhance competition, improve access and quality, and decrease health care costs in both the public and private sectors.

This comment supports the IFC’s provisions to reduce or eliminate restrictive Medicare payment requirements for telehealth and communication technology-based services (“CTBS”) during the current public health emergency,³ thus mitigating the exposure risk of patients and health care professionals. We also make a number of suggestions to further reduce restrictions that may be unnecessary for safety and quality. Finally, we suggest that CMS use the experience it gains from reimbursing a broader set of telehealth services, providers, and CTBS during the public health emergency to develop additional empirical evidence on the effects of these policies and to consider whether some of the regulatory revisions discussed in this letter should be made permanent.⁴ Doing so could benefit patients, practitioners, and the health care system as a whole.

I. Interest and Experience of the Federal Trade Commission

The FTC is charged under the FTC Act with preventing unfair methods of competition and unfair or deceptive acts or practices in or affecting commerce.⁵ Competition is at the core of America's economy,⁶ and vigorous competition among sellers in an open marketplace gives consumers the benefits of lower prices, higher quality products and services, and increased innovation. Because of the importance of health care competition to the economy and consumer welfare, anticompetitive conduct in health care markets has long been a key focus of FTC law enforcement,⁷ research,⁸ and advocacy.⁹ Many of our recent advocacy comments have addressed scope of practice and supervision requirements that may unnecessarily limit the range of procedures or services a practitioner may provide, or unnecessarily restrict a particular type of practitioner from competing in the market.¹⁰

Telehealth is an area of particular interest to the FTC because of its potential to increase the supply of available practitioners, encourage competition, and improve access to affordable, quality health care. In a 2004 report, the federal antitrust agencies considered the competitive effects of state restrictions on the interstate practice of telemedicine.¹¹ The central finding of that analysis remains applicable today: "When used properly, telemedicine has considerable promise as a mechanism to broaden access, lower costs, and improve health care quality."¹² More recently, the Commission reiterated these benefits when it closed an investigation of the Texas Medical Board after the Texas legislature enacted a law overriding the Board's rules restricting the practice of telehealth.¹³ FTC staff also submitted comments to the Alaska legislature and the Department of Veterans Affairs ("VA") supporting proposals to allow licensed physicians to provide telehealth services across state lines.¹⁴ FTC staff continued to support license portability for telehealth in the 2018 report, *Options to Enhance Occupational License Portability*.¹⁵ FTC staff also commented on telehealth issues in regard to a Washington state bill and regulations proposed by three Delaware occupational licensing boards.¹⁶ These letters recommend that health care practitioners be allowed to use their own judgment in deciding whether the use of telehealth services is appropriate under the circumstances. The conclusions of the agencies' 2004 report and these recent FTC staff comments support reducing unjustified barriers to telehealth and underpin this comment.

II. The Interim Final Rule: Regulatory Changes to the Current Framework for Telehealth in Response to the COVID-19 Public Health Emergency

Telehealth, if broadly deployed, has the potential to mitigate challenges in access to health care arising from an aging population, healthcare workforce shortages, and geographic and other mal-distributions of providers. Telehealth can also address the needs of urban underserved patients who experience provider shortages arising from economic disparities and limited mobility, to the extent that these patients can access the necessary technology.¹⁷

Telehealth can potentially increase the supply of accessible practitioners and thereby enhance price and non-price competition, reduce transportation expenditures, and improve access to and choice of quality care.¹⁸ Many experts consider reducing restrictions on Medicare reimbursement of telehealth services especially important for fulfilling telehealth's potential, not only because Medicare places substantial limitations on using telehealth services, but also because Medicare influences the reimbursement policies of state Medicaid programs and private payers.¹⁹

FTC staff support CMS as it reduces restrictions on Medicare reimbursement of telehealth services during this public health emergency, thus mitigating the exposure risk of patients and health care professionals. This comment provides a competition perspective on Medicare payment of telehealth services both during and after the public health emergency. In particular, we consider the IFC's provisions with regard to six categories: 1) eliminating originating site and geographic requirements, thus allowing telehealth services to be provided to patients at any location, including the home; 2) expanding the types of services that may be furnished by telehealth; 3) providing for access to therapy services furnished by providers who are not statutorily authorized telehealth providers; 4) expanding the use of telehealth telecommunication modalities, including audio-only telephone; 5) allowing CTBS for new as well as established patients; and 6) allowing direct supervision required under Medicare's "incident to" billing rules to be carried out via interactive telecommunications technology.

A. Allowing Telehealth Services to be Provided to Patients at Any Location, Including the Home

We support CMS's use of its waiver authority to allow Medicare to reimburse telehealth services provided to a patient at any location, including the patient's residence, during this public health emergency.²⁰ This temporarily eliminates a major and longstanding barrier to providers of telehealth services.²¹ Ordinarily, Medicare's fee-for-service program pays providers for telehealth services only when patients are located at certain types of health care facilities ("originating sites"),²² and the facilities must be located in rural areas with a shortage of health professionals.²³ Therefore, Medicare does not reimburse for telehealth services furnished to a patient at a residence, or in a metropolitan area. By restricting reimbursement, Medicare reduces the supply of providers, access to telehealth services, and competition at such locations.

Allowing reimbursement of telehealth services in the home, in any geographic area, will greatly increase the ability to provide care safely during the pandemic. To mitigate exposure risk from COVID-19, the greatest need for telehealth services may be in densely populated urban areas where COVID-19 cases are common.²⁴ As a result of shelter-in-place orders, both uninfected and infected patients are often at their homes or other residences.²⁵ By allowing telehealth services to be provided to patients anywhere, including at their residences, the waiver allows more patients to receive services without jeopardizing their health or the health of the professionals who provide care.²⁶

Although the public health emergency necessitated immediate removal of the geographic and originating site requirements, longstanding and broad support for eliminating these requirements existed before the pandemic.²⁷ These requirements preclude reimbursement for services provided to urban beneficiaries with limited access to in-person care because of mobility, economic, or other barriers, as well as rural populations who may live far from an authorized originating site. The requirements inhibit entry of telehealth providers and limit patients' access to care and choice of provider. Accordingly, the requirements could limit competition among practitioners, potentially reducing the quality and amount of care and increasing its costs.

For these reasons, we strongly support suspending these requirements during the public health emergency, and we urge CMS to consider whether they should be permanently eliminated. Doing so would be consistent with the administration's 2018 report, *Reforming America's Healthcare System Through Choice and Competition*, which recommends that

“Congress should consider proposals modifying geographic location and originating site requirements in Medicare fee-for-service that restrict the availability of telehealth services to Medicare beneficiaries in their homes and in most geographic areas.”²⁸ Experience during the pandemic with reimbursing telehealth services not subject to originating site and geographic location requirements should be helpful in evaluating whether it would also be beneficial to eliminate these requirements permanently after the emergency ends.

B. Expanding the Types of Services that May be Furnished by Telehealth

We also support the expansion of the types of Medicare-reimbursable telehealth services set forth in the IFC. By improving access to telehealth services and providers, patients, practitioners, and the Medicare program should benefit. Ordinarily, Medicare’s fee-for-service program restricts the services that can be provided via telehealth. The statute limits reimbursable telehealth services to “professional consultations, office visits, and office psychiatry services,”²⁹ which has resulted in a relatively short and narrow list of reimbursable telehealth services.³⁰ The Secretary of the U.S. Department of Health and Human Services (“HHS”), however, may authorize additional services as warranted.³¹

To mitigate the risks of COVID-19 exposure for both patients and health care professionals, CMS has authorized more than 80 additional types of telehealth services during this public health emergency, including emergency department visits, initial nursing facility and discharge visits, intensive care unit services, and home visits.³² CMS does not consider the newly authorized services to be similar to the original, statutorily authorized services. Indeed, under normal procedures, CMS probably would not approve these procedures for reimbursement without a clinical study demonstrating patient benefit.³³ But, in the face of this public health emergency where exposure risks are significant, CMS authorized the use of telehealth for these services.³⁴

This vast expansion of the types of reimbursable services eliminates a major restriction on telehealth care and allows telehealth services to be provided in novel and innovative ways that could improve triage, diagnosis, and treatment of COVID-19 patients. It also will reduce the coronavirus exposure risks of non-COVID-19 patients and health care professionals.³⁵ Without this expansion of reimbursable telehealth services, it could be difficult or impossible to provide many of the newly authorized services safely. By allowing practitioners to provide services remotely, especially in areas of need that are far away, the change likely increases beneficiaries’ access to needed care during the public health crisis. The change also could enhance the quality of services provided, increase competition, and reduce costs.

The expansion of reimbursable telehealth services during this public health emergency should highlight the benefits and drawbacks of using telehealth to provide different types of services. As a result, CMS will be in a better position to decide whether to continue some or all of the added services after this emergency ends.³⁶

C. Access to Therapy Services Furnished by Providers Who Are Not Statutorily Authorized Telehealth Providers

Another major barrier to telehealth uptake is Medicare’s restrictions on the types of practitioners who are authorized to be reimbursed for telehealth services. Because of this statutory limitation, the IFC does not authorize payment to therapy practitioners, such as physical therapists, occupational therapists, and speech-language pathologists.³⁷ Nevertheless, we support

CMS's use of its waiver authority after the IFC was issued to designate these and other practitioners as authorized Medicare telehealth services providers. We believe this will enhance the supply of and access to therapy services.

Therapy practitioners are able to provide many services to patients through telehealth. For example, speech-language pathologists can screen and treat students using telepractice, and audiologists can carry out diagnostic hearing assessments and hearing aid programming remotely.³⁸ Physical therapists, occupational therapists, speech-language pathologists, audiologists, and others provide telerehabilitation care, which helps patients with stroke, head and spinal injury, neurological disorders, and other diseases regain everyday skills and maintain quality of life. In fact, telerehabilitation has the advantage of allowing the therapist to tailor care to the patient's home or residence.³⁹

Although the IFC sets forth two approaches to improving remote access to therapy services, neither approach authorizes therapy practitioners to be reimbursed for telehealth services. Specifically:

- First, the IFC authorizes payment for certain telehealth therapy services, such as physical therapy, occupational therapy, and speech-language pathology therapy, but only when the services are provided by the statutorily authorized telehealth providers, such as physicians, nurse practitioners, or physician assistants.⁴⁰ Limiting reimbursement for telehealth therapy services to practitioners who do not ordinarily deliver these types of services, and lack the necessary expertise, is unlikely to facilitate remote access to safe and effective therapy services.⁴¹
- Second, CMS authorizes therapy professionals to provide some remotely delivered CTBS, which are services that are routinely furnished using a telecommunications system but are not considered telehealth services. Examples include remote evaluation of online videos and virtual check-in services.⁴² But such services, referred to as “sometimes therapy” by CMS, do not facilitate continuing care by non-authorized providers.⁴³

CMS subsequently used the broad waiver authority granted under Section 3703 of the Coronavirus Aid, Relief, and Economic Security Act (“CARES Act”),⁴⁴ which was enacted after the IFC was written, to allow therapy professionals, including physical therapists, occupational therapists, speech-language pathologists, audiologists, and all professionals eligible to bill Medicare, to be authorized Medicare telehealth providers during this public health emergency.⁴⁵ Doing so allows a variety of therapy services to be delivered with little risk of exposure to COVID-19, benefiting both patients and practitioners.

Based on its experience with reimbursing therapy practitioners for telehealth services during the current public health crisis, CMS should consider permanently adding these practitioners to the list of authorized telehealth providers. There is longstanding support for Medicare reimbursement of therapy practitioners and other practitioners not ordinarily eligible for reimbursement of telehealth services.⁴⁶ Making them authorized telehealth providers on a permanent basis could enhance the availability of therapists, access to care, choice of provider, competition, and quality, and also could reduce costs. Such improvements may especially benefit rural and underserved communities, as well as patients for whom travel is difficult.⁴⁷

D. Telehealth Telecommunication Modalities, Including Audio-Only Telephone

We support CMS's use of its waiver authority under the CARES Act to expand the list of reimbursable telehealth services that may be provided by audio-only telephone.⁴⁸ Although not prohibited by statute, services provided by audio-only telephone are not ordinarily reimbursable telehealth services under Medicare. Allowing Medicare to pay for certain audio-only telephone care as telehealth services could increase access, choice, and competition in the supply of telehealth services.

Under existing Medicare regulations, telehealth services must be provided by a live, interactive telecommunications system with both audio and video components.⁴⁹ The IFC did not change the regulatory restriction.⁵⁰ Although the use of smartphones and other devices with audio/video capability is widespread, not all patients have smartphones, or a suitable computer or device with webcam and broadband access. Indeed, Medicare beneficiaries, the vast majority of whom are over 65 years of age, are in the demographic least likely to have or use audio/video systems. Rural and lower-income Americans may also lack suitable equipment.⁵¹ Even medical practices ramping up their telehealth capabilities have encountered difficulties such as dropped calls, poor quality, and lags when providing video visits, and have found that audio-only telephone calls form the basis of much of their care.⁵²

CMS acknowledges in the IFC that during the pandemic, audio-only telephone communication may be the only clinically appropriate option because two-way audio/video technology might be unavailable.⁵³ Accordingly, the IFC authorizes limited reimbursement of audio-only telephone care as a non-telehealth service routinely provided by a telecommunications system.⁵⁴ But, as discussed above, restrictions on reimbursement of such CTBS may limit its utility for continuing care.⁵⁵

Allowing reimbursement for care provided by audio-only telephone as a telehealth service potentially increases access to safe and effective care and enhances competition among providers, especially in rural and underserved areas where access to audio/video devices and broadband service may be limited.⁵⁶ We suggest that CMS consider whether such benefits support continuing telehealth reimbursement of audio-only telephone services after this crisis, or whether its experience with expanded telehealth reimbursement of these services reveals legitimate health and safety concerns that could justify discontinuing or narrowing such reimbursement after this public health emergency ends.

E. Medicare's Established Patient Requirement for Non-Telehealth Communication Technology-Based Services ("CTBS")

Ordinarily, Medicare reimbursement of CTBS is available only when a practitioner cares for an established patient. There must be an established patient-practitioner relationship before a practitioner furnishes CTBS services such as virtual check-ins, remote physiologic monitoring, or telephone evaluation/management services.⁵⁷ Medicare generally defines an established patient as one that a practitioner, or another practitioner in the same practice, has seen in person during the past three years.⁵⁸ Because rigid established patient and in-person examination requirements restrict the supply of available practitioners and may be unnecessary to protect consumers, we support CMS's decision to enhance access to certain CTBS services during this public health emergency, either by modifying CMS's requirements to allow these services to be provided to new as well as established patients, or by exercising its enforcement discretion.⁵⁹ As the IFC explains, brief communications and other services categorized as CTBS might reduce the

need for a risky in-person visit and “should be available to as large a population of Medicare beneficiaries as possible.”⁶⁰

More generally, by excluding reimbursement for services provided to new patients who have not seen a practitioner in person, the “established patient” requirement restricts care from direct-to-consumer (“DTC”) telehealth companies. Patients initiate contact with DTC companies, which typically provide care around-the-clock, using practitioners located anywhere, often beyond the range of a patient’s established in-person provider.⁶¹ By excluding such distant practitioners from providing CTBS, the “established patient” requirement restricts the supply of providers of telecommunication-based services, and may be unnecessary to protect consumers. Similarly, the “established patient” requirement prevents practitioners in traditional office settings—whether in the patient’s geographic area, or distant from it—from providing CTBS to new patients.

As discussed in a number of FTC staff advocacy comments, in-person examination requirements prevent licensed health care providers from providing telehealth care that they otherwise would deem appropriate. Such restrictions potentially reduce competition, innovation, consumer choice, and the supply and quality of care, and may also increase price. Accordingly, FTC staff advocacy comments have opposed proposed laws and regulations that prohibit the use of telehealth for initial, as well as subsequent evaluations. Rather, FTC advocacy has favored flexible provisions that allow the licensed practitioner in the best position to weigh access, health, and safety considerations to decide whether to use telehealth. Such policies, which allow the patient-practitioner relationship to be established by telehealth and typically hold the practitioner to an in person standard of care, are supported by several physicians’ organizations.⁶²

We suggest that after the public health emergency ends, CMS consider allowing licensed practitioners to decide whether to provide at least some CTBS services to new as well as established patients. This approach would better promote competition and access to safe and affordable care.

F. Allowing Direct Supervision Required Under Medicare’s “Incident To” Billing Rules to be Carried Out Via Telecommunications Technology

In many circumstances, Medicare requires certain types of practitioners to be supervised at particular levels as a condition for payment for their services. Under Medicare’s “incident to” billing provisions, physicians can bill Medicare for services provided by nonphysician practitioners under their *direct supervision*,⁶³ such as advanced practice registered nurse practitioners (“APRNs”) and physician assistants (“PAs”). Direct supervision, typically considered the most restrictive level of supervision, means that a physician or other supervisor must be present in the office suite and immediately available to provide assistance and direction.⁶⁴ The IFC temporarily relaxes the direct supervision requirement during the public health emergency by changing the definition of direct supervision to allow remote supervision using audio/video telecommunications technology, thereby reducing COVID-19 exposure risk.⁶⁵

Although the change reduces exposure risk, it does not fully alleviate other potential negative effects of direct supervision requirements—for example, on practitioner efficiency, access to care, and practitioner supply. We suggest that CMS eliminate the direct supervision requirement for nonphysician practitioners such as APRNs and PAs, deferring instead to any

state supervision requirements. In the many states that allow APRNs and PAs to practice with less stringent supervision, this change would directly benefit healthcare consumers.

Unduly restrictive supervision requirements directly impact access to nonphysician practitioners by limiting their supply where supervisors are scarce—for example, in areas where there is a shortage of health care professionals and in rural and underserved settings where supervising physicians are often unavailable.⁶⁶ Direct supervision, which requires a supervisor to be on site, is particularly restrictive, barring affiliated practitioners from practicing in places where a supervisor is not physically present.⁶⁷ Because practitioners could not care for homebound patients in underserved areas that lack supervising physicians, Medicare started to allow general supervision, which does not require a supervisor to be on site, for “incident to” services provided to homebound patients.⁶⁸

To further address such issues, in 1997, Congress granted nonphysician practitioners the ability to bill Medicare directly in all practice settings, under reduced supervision levels such as general supervision or collaboration.⁶⁹ But many noninstitutional settings, like offices, still use “incident to” billing requiring direct supervision due to the incentives created by Medicare’s reimbursement rate structure.⁷⁰ In these settings, physicians may use “incident to” billing under Medicare for services provided by PAs, nurse practitioners (“NPs”), and clinical nurse specialists (“CNSs”) under their direct supervision at 100 percent of the physician fee schedule rate, rather than the 85 percent rate used if these practitioners were to bill Medicare directly.⁷¹ Because of this payment differential, employers of these nonphysician practitioners have a financial incentive to use “incident to” billing, thus triggering the direct supervision requirement.⁷²

Allowing physicians to directly supervise nonphysician practitioners remotely using telecommunications is unlikely to eliminate the restrictive impacts of direct supervision on access to care, practitioner efficiency, and competition, especially during the public health emergency. During the pandemic, the capacity of supervising physicians and nonphysician practitioners to provide care may be stretched thin. “Incident to” billing requires “the physician’s continuing active participation in and management of the course of treatment,”⁷³ even when this level of supervision may not be necessary to ensure patient health and safety, potentially resulting in inefficient duplication of efforts by supervisors and supervisees.⁷⁴ According to the Medicare Payment Advisory Commission (“MedPac”), “these billing rules could keep physicians from optimally structuring their practice for efficiency and access,” for example “by requiring APRNs and PAs to treat established patients when their time might be better spent dealing with new patients with certain injuries or illnesses.”⁷⁵ Even if supervision is provided by audio/video telecommunication,⁷⁶ it is still unnecessary and counterproductive to require physicians to take time from patient care to directly supervise PAs, APRNs, and other nonphysician practitioners who have extensive education and training and who, under state law, are often allowed to work independently or with lower levels of supervision.

HHS recognized this potential for supervision requirements to impair the efficiency of the COVID-19 response when it recommended that states “[t]emporarily suspend . . . any requirements for written agreements to meet supervision or collaboration requirements, in order to avoid significant delays in the provision of services.” Acknowledging the effects of requirements for an on-site supervisor, HHS also recommended that states “temporarily waive any requirements that the supervising physician be physically co-located with or within a certain geographic distance to the NP or PA who he or she is supervising.”⁷⁷ In its *Guidance to States*, HHS summed up its position by recommending that states “allow health care professionals like

nurse practitioners (NPs), other registered nurses, and physician assistants (PAs) to practice to the fullest extent of their license and without restrictive supervision requirements.”⁷⁸

Similarly, in changing the required level of supervision for hospital outpatient therapeutic services from direct to general in 2020, CMS explained that direct supervision “places an additional burden on providers that reduces their flexibility to provide medical care,” especially in rural hospitals where there may be insufficient staff to furnish direct supervision. Moreover, in CMS’s experience, “Medicare providers will provide a similar quality of hospital outpatient therapeutic services, regardless of whether the minimum level of supervision required under the Medicare program is direct or general.”⁷⁹

Notably, Medicare’s direct supervision requirement for “incident to” billing operates in addition to any state supervision or collaboration requirements. Most state requirements were much less restrictive than Medicare’s requirement even before states reduced required supervision in response to the public health emergency. Before the COVID-19 crisis, about half the states allowed nurse practitioners to practice independently, and a smaller number required supervision or collaboration agreements.⁸⁰ For PAs, while states generally required a specific supervisory or collaborative relationship with a physician, few required on-site supervision.⁸¹

We recommend that CMS amend its Medicare rules to eliminate direct supervision of nonphysician practitioners in noninstitutional settings, and rely instead on each state’s supervision or collaboration requirements to determine the level of oversight. For purposes of Medicare, the rules should allow any state-required supervision or collaboration to be provided by telecommunication systems as authorized by state law.⁸²

Eliminating Medicare’s direct supervision requirement could improve access to health care professionals and services, especially in health professional shortage and underserved areas. Accordingly, we urge CMS to consider whether there are well-founded health and safety justifications for retaining the direct supervision requirement.

More generally, we recommend that CMS ask Congress to eliminate the “incident to” billing provision, which is a vestige of a time when advanced practice registered nursing and physician assisting were nascent professions, and when state laws governing supervision of such practitioners were more restrictive.⁸³ Instead, nonphysician practitioners should be required to bill Medicare directly, consistent with the recommendations of the report, *Reforming America’s Healthcare System Through Choice and Competition*,⁸⁴ and the 2019 *MedPac Report to Congress*.⁸⁵ Doing so could improve provider efficiency and beneficiary access to care and potentially reduce Medicare spending and beneficiary financial liability.⁸⁶

III. Conclusion

By connecting widely separated providers and patients, telehealth can alleviate primary care and specialty shortages, especially in rural areas. Telehealth can also address the needs of urban patients who have difficulty accessing providers due to economic disparities and limited mobility. Reducing or eliminating certain reimbursement requirements could enhance the availability of telehealth providers; increase competition on price, quality, and innovation; and help improve outcomes and control costs.

Reducing restrictions on reimbursement of telehealth and other telecommunications-based services is essential during the public health emergency to allow health care professionals

to provide care safely to Medicare beneficiaries, and to support and enhance the vast expansion of telehealth care that is already underway.

We commend CMS and support the IFC’s provisions to reduce or eliminate restrictive Medicare telehealth payment provisions. At the same time, we respectfully suggest that CMS consider, in light of existing empirical evidence and any new evidence generated by these temporary measures, whether our suggestions to further reduce such restrictions, both during and after the public health emergency, would help to provide care safely, and also better promote competition and access to safe and affordable care.

We appreciate your consideration.

Respectfully submitted,

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¹ This letter expresses the views of staff in the Federal Trade Commission’s Office of Policy Planning, Bureau of Economics, Bureau of Competition, and Office of the General Counsel. The letter does not necessarily represent the views of the Federal Trade Commission or of any individual Commissioner. The Commission, however, has authorized us to submit these comments.

² Interim Final Rule with Comment Period, Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency, 85 Fed. Reg. 19,230 (April 6, 2020) (to be codified at 42 C.F.R. pts. 400, 405, 409-10, 412, 414-15, 417-18, 421-23, 425, 482, 510). The regulations became effective on March 31, 2020, and applicable on March 1, 2020. *See id.* at 19,230.

³ Pursuant to the Public Health Service Act § 319 (42 U.S.C. § 247d), Alex M. Azar II, Secretary of Health and Human Services, determined on Jan. 31, 2020, that a nationwide public health emergency (“PHE”) existed since

Jan. 27, 2020 due to the 2019 Novel Coronavirus. The Secretary renewed the PHE on April 21, 2020. *See* Renewal of Determination That a Public Health Emergency Exists, <https://www.phe.gov/emergency/news/healthactions/phe/Pages/covid19-21apr2020.aspx>. A PHE lasts until the Secretary determines it is over, or a maximum of 90 days, but can be renewed as necessary. 42 U.S.C. § 247d(a). When a PHE has been declared, under section 1135 of the Social Security Act the Secretary can waive or modify certain Medicare and Medicaid requirements to ensure the availability of goods and services for those programs and to allow reimbursement of providers who cannot comply with certain requirements. A Presidential declaration of an emergency or disaster under the National Emergencies Act, 50 U.S.C. § 1601 *et seq.*, is also necessary to exercise this authority. *See* 42 U.S.C. § 1320b-5. On Mar. 13, 2020, President Trump declared a National Emergency effective March 1, 2020. *See* Proclamation No. 9994, 85 Fed. Reg. 15,337 (Mar. 18, 2020).

⁴ We take no position on the IFC’s regulatory revisions not discussed in this letter.

⁵ Federal Trade Commission Act, 15 U.S.C. § 45.

⁶ *Standard Oil Co. v. FTC*, 340 U.S. 231, 248 (1951) (“The heart of our national economic policy long has been faith in the value of competition.”).

⁷ *See generally* MARKUS H. MEIER ET AL., FTC, OVERVIEW OF FTC ACTIONS IN HEALTH CARE SERVICES AND PRODUCTS, <https://www.ftc.gov/tips-advice/competition-guidance/industry-guidance/health-care> (most recent version under “Core Health Care Competition Documents”).

⁸ *See, e.g.*, FTC & U.S. DEP’T OF JUSTICE, IMPROVING HEALTH CARE: A DOSE OF COMPETITION (2004), <http://www.ftc.gov/reports/healthcare/040723healthcarerept.pdf>.

⁹ FTC and staff advocacy can include letters or comments addressing specific policy issues, Commission or staff testimony before legislative or regulatory bodies, amicus briefs, and reports. *See, e.g.*, Comment from FTC Staff to Thomas E. Brinkman, Jr., Representative, Ohio House of Representatives (Jan. 9, 2020), https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-ohio-house-representatives-concerning-ohio-house-bill-177/v200005ohiohb177aprnscomment.pdf (discussing the likely procompetitive effects of a Bill that would expand the scope of practice of APRNs in Ohio by ending Ohio’s mandatory written collaborative agreement requirement); Brief of Amicus Curiae FTC in Support of No Party, In re Nexium (Esomeprazole) Antitrust Litig., No. 15-2005 (1st. Cir. Feb. 12, 2016), https://www.ftc.gov/system/files/documents/amicus_briefs/re-nexium-esomeprazole-antitrust-litigation/160212nexiumbrief.pdf (explaining that a reverse payment from a brand-name drugmaker that is used to settle patent litigation can violate the antitrust laws if it induces a generic drugmaker to abandon its patent challenge and stay out of the market); FTC STAFF, POLICY PERSPECTIVES: COMPETITION AND THE REGULATION OF ADVANCED PRACTICE NURSES (“APRNs”) (2014), <https://www.ftc.gov/system/files/documents/reports/policy-perspectives-competition-regulation-advanced-practice-nurses/140307aprnpolicypaper.pdf> [hereinafter FTC STAFF POLICY PERSPECTIVES] (presenting an overview of FTC staff comments regarding APRNs, and an in depth analysis of the competitive effects of statutes and rules governing APRN scope of practice and supervision).

¹⁰ *See, e.g.*, Comment from FTC Staff to Daniel R. Hawkins, Rep., Kansas House of Representatives (Jan. 9, 2020), https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-kansas-house-representatives-concerning-kansas-house-bill-2412/v200006kansashb2412aprnscomment.pdf (commenting on a bill that would eliminate a written collaboration agreement requirement for APRNs, and shift regulatory authority over APRNs from the nursing board to the medical board); Comment from FTC Staff to the Dep’t of Veterans Affairs (July 25, 2016), https://www.ftc.gov/system/files/documents/advocacy_documents/comment-staff-ftc-office-policy-planning-bureau-competition-bureau-economics-department-veterans/v160013_staff_comment_department_of_veterans_affairs.pdf (supporting proposed rule that would allow APRNs to provide VA services without physician oversight).

¹¹ *See* FTC & U.S. DEP’T OF JUSTICE, *supra* note 8, ch. 2, at 30 (section on “State Restrictions on the Interstate Practice of Telemedicine”).

¹² *Id.* at Executive Summary at 23.

¹³ See Statement of the FTC on Commission Vote to Close Investigation of Texas Medical Board’s Conduct (June 21, 2017), https://www.ftc.gov/system/files/documents/public_statements/1225993/1510180_texas_medical_board_statement_of_the_commission_6-21-17.pdf.

¹⁴ See Comment from FTC Staff to the Director, Regulation Pol’y and Mgmt., Dep’t of Veterans Affairs (Nov. 1, 2017), https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-department-veterans-affairs-regarding-its-proposed-telehealth-rule/v180001vatelehealth.pdf (supporting the VA’s proposed rule that would clarify the authority of VA health care providers to provide telehealth services to or from non-federal sites regardless of whether the provider is licensed in the state where the patient is located); Comment from FTC Staff to Steve Thompson, Representative, Alaska State Legislature (Mar. 25, 2016), <https://www.ftc.gov/policy/policy-actions/advocacy-filings/2016/03/ftc-staff-comment-alaska-state-legislature-regarding> (regarding telehealth provisions in Senate Bill 74, which would allow licensed Alaska physicians located out of state to provide telehealth services).

¹⁵ See FTC STAFF, POLICY PERSPECTIVES: OPTIONS TO ENHANCE OCCUPATIONAL LICENSE PORTABILITY (2018), <https://www.ftc.gov/reports/options-enhance-occupational-license-portability>.

¹⁶ See Comment from FTC Staff to Paul Graves, Representative, Washington State Legislature (Feb. 9, 2018), <https://www.ftc.gov/policy/advocacy/advocacy-filings/2018/02/ftc-staff-comment-washington-state-rep-paul-graves> (regarding a bill proposing an in-person examination requirement that would restrict telehealth eye care); Comment from FTC Staff to the Del. Bd. of Speech/Language Pathologists, Audiologists & Hearing Aid Dispensers (Nov. 29, 2016), https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-delaware-board-speech/language-pathologists-audiologists-hearing-aid-dispensers-regarding-its-proposed-revisions-its/161130_ftc_dealers_final_.pdf; Comment from FTC Staff to the Del. Bd. of Dietetics/Nutrition (Aug. 16, 2016), https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-delaware-board-dietetics/nutrition-regarding-its-proposed-telehealth-regulation/de_telehealth-nutrition-v160015.pdf; and Comment from FTC Staff to the Del. Bd. of Occupational Therapy Practice (Aug. 3, 2016), https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-delaware-board-occupational-therapy-concerning-its-proposed-telehealth-regulation/v160014_delaware_ot_proposed_advocacy.pdf.

¹⁷ See generally Karen Schulder Rheuban & Scott Shipman, *Workforce, Definitions, and Models*, in UNDERSTANDING TELEHEALTH ch. 2 (Karen S. Rheuban & Elizabeth A. Krupinski, eds., 2018) (“Telehealth is an essential tool to address the significant challenges of access to high-quality care, regardless of patient location. Telehealth tools and models of care delivery have been demonstrated to favorably affect both acute and chronic illnesses, reduce disparities, mitigate shortages, improve population health, and lower the costs of care.”); Am. Acad. of Pediatrics, *Policy Statement: The Use of Telemedicine to Address Access and Physician Workforce Shortages*, 136 PEDIATRICS 202, 203 (2015) (urban as well as rural children “face significant disparities in access and time-distance barriers, which could be partly alleviated by the use of telehealth”); Hilary Daniel & Lois Snyder Sulmasy, *Policy Recommendations to Guide the Use of Telemedicine in Primary Care Settings: An American College of Physicians Position Paper*, 163 ANN. INT. MED. 787, app. (2015) [hereinafter Am. College of Physicians Position Paper] (“Limited access to care is not an issue specific to rural communities; underserved patients in urban areas have the same risks as rural patients if they lack primary or specialty care”); Rashid L. Bashshur et al., *The Empirical Foundations of Telemedicine Interventions for Chronic Disease Management*, 20 TELEMED. & E-HEALTH 769, 770 (2014) (“Differences in access to care reflect economic, geographic, and functional as well as social, cultural, and psychological factors [M]any residents of the inner city have limited access to medical resources for economic reasons.”). Although telehealth can improve access to care, some underserved patients may not have the necessary technology, or be limited in their use of it. See *infra* note 51 and accompanying text.

¹⁸ See, e.g., Comment from FTC Staff to Steve Thompson, *supra* note 14.

¹⁹ See, e.g., Jack Resneck et al., *Patients, Their Physicians, and Telehealth*, in UNDERSTANDING TELEHEALTH ch. 21, 272-73 (Karen S. Rheuban & Elizabeth A. Krupinski, eds., 2018) (“Physicians and health systems consistently cite lack of coverage and payment for services delivered via telemedicine as one of the obstacles to its adoption” and Medicare “has lagged substantially behind in terms of coverage and payment of telemedicine services, largely . . . due to restrictive provisions of the federal law governing the program”); Am. College of Physicians Position Paper,

supra note 17 (“One of the most significant challenges to wide-spread telemedicine adoption is reimbursement.”); Bryan L. Burke et al., American Academy of Pediatrics, *Telemedicine: Pediatric Applications*, 136 PEDIATRICS e294, e303 (2015) (“The most significant barriers are payment, licensing across state borders, and liability.”).

²⁰ On March 17, 2020, CMS announced the temporary expansion of telehealth services pursuant to waiver authority added under the Social Security Act § 1135(b)(8) by the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020, Pub. L. No. 116-123, 134 Stat. 156 (2020). The Act provided authority to waive both the geographic and originating site requirements temporarily during an emergency. Pursuant to the waiver, any type of residence, such as homes or assisted living facilities, would be an authorized originating site. *See* IFC, 85 Fed. Reg. at 19,232-33; CMS, ADDITIONAL BACKGROUND: SWEEPING REGULATORY CHANGES TO HELP U.S. HEALTHCARE SYSTEM ADDRESS COVID-19 PATIENT SURGE (Mar. 30, 2020), <https://www.cms.gov/newsroom/factsheets/additional-backgroundsweeping-regulatory-changes-help-us-healthcare-system-address-covid-19-patient>.

²¹ *See, e.g.*, U.S. DEP’T OF HEALTH & HUMAN SERVICES, U.S. DEP’T OF THE TREASURY, & U.S. DEP’T OF LABOR, REFORMING AMERICA’S HEALTHCARE SYSTEM THROUGH CHOICE AND COMPETITION 41-42 (Dec. 2018), <https://www.hhs.gov/sites/default/files/Reforming-Americas-Healthcare-System-Through-Choice-and-Competition.pdf> [hereinafter CHOICE & COMPETITION REPORT]; Gary Capistrant, *Medicare Coverage and Reimbursement Policies*, in UNDERSTANDING TELEHEALTH ch. 23, 285-86 (Karen S. Rheuban & Elizabeth A. Krupinski, eds., 2018) (Medicare telehealth coverage is restrictive largely because its “telehealth provisions reflect a snapshot of the late 1990s”).

²² *See* 42 U.S.C. § 1395m(m)(4)(C)(ii); 42 C.F.R. § 410.78(b)(3) (a beneficiary receiving telehealth services must be located in a qualifying originating site, such as a practitioner’s office, a hospital, a rural health clinic, a federally qualified health center, a skilled nursing facility, or a community mental health center). Beginning in 2019, the home was authorized as a telehealth originating site for end stage renal disease-related clinical assessments and treatment of substance use disorders. *See* 42 U.S.C. § 1395m(m)(4)(C)(ii)(X); 42 C.F.R. § 410.78(b)(3).

²³ *See* 42 U.S.C. § 1395m(m)(4)(C)(i); 42 C.F.R. § 410.78(b)(4). Regulatory changes loosen these requirements slightly by including certain rural census tracts within Metropolitan Statistical Areas and setting covered geographic areas on an annual basis. *See* 78 Fed. Reg. 74,230, 74,400-402, 74,812 (2013).

²⁴ *See, e.g.*, CDC COVID-19 Response Team, *Geographic Differences in COVID-19 Cases, Deaths, and Incidence—United States, Feb. 12-April 7, 2020*, 69 MORB. MORT. WKLY REP’T 465, 467 (2020) (“Because COVID-19 is primarily transmitted by respiratory droplets, population density might also play a significant role in the acceleration of transmission. Cumulative incidence in urban areas like NYC and DC exceeds the national average.”). Rural locations, however, experience their own significant challenges due to older average age, fewer resources, and a population with underlying health conditions. *See, e.g.*, RACHEL FEHR ET AL., COVID-19 IN RURAL AMERICA—IS THERE CAUSE FOR CONCERN?, KAISER FAMILY FOUNDATION (Apr. 30, 2020), <https://www.kff.org/other/issue-brief/covid-19-in-rural-america-is-there-cause-for-concern/#>.

²⁵ *See, e.g.*, Exec. Order No. 20-03-30-01 of the Governor of the State of Maryland (March 30, 2020) (prohibiting large gatherings and certain businesses, and “additionally requiring all persons to stay at home”); Exec. Order No. N-33-20 of the Governor of the State of California (Mar. 19, 2020) (ordering “all individuals living in the State of California to stay home or at their place of residence except as needed . . .”).

²⁶ *See, e.g.*, Judd E. Hollander & Brendan G. Carr, *Virtually Perfect? Telemedicine for Covid-19*, 382 N. ENGL. J. MED. 1679 (2020) (describing benefits of using telemedicine during the pandemic).

²⁷ *See, e.g.*, Jack Resneck et al., *supra* note 19, at ch. 21, 273-74 (“support for expanded access for all Medicare beneficiaries has grown rapidly among major health care providers and many policy makers” and the American Medical Association has urged CMS to exercise authorities to “[r]emove the current geographic and originating site restrictions that prevent delivery of what would otherwise be covered services in urban and suburban areas”); LATOYA THOMAS & GARY CAPISTRANT, AM. TELEMEDICINE ASS’N, STATE TELEMEDICINE GAPS ANALYSIS: COVERAGE & REIMBURSEMENT 6 (2017), <https://legacy.americantelemed.org/main/policy-page/state-telemedicine-gaps-reports> (“artificial barriers such as geographic discrimination and restrictions on provider and patient settings and technology type are harmful and counterproductive”); Am. College of Physicians Position Paper, *supra* note 17 at 789 (“ACP supports lifting geographic site restrictions that limit reimbursement of telemedicine and telehealth

services by Medicare”); Am. Hospital Ass’n, *Realizing the Promise of Telehealth: Understanding the Legal and Regulatory Challenges*, TRENDWATCH 14 (May 2015), <http://www.aha.org/research/reports/tw/15may-tw-telehealth.pdf> (urging federal and state policymakers to “[e]liminate geographic and setting location requirements”).

²⁸ CHOICE & COMPETITION REPORT, *supra* note 21 at 42.

²⁹ 42 U.S.C. § 1395(m)(m)(4)(F).

³⁰ *See e.g.*, Jack Resneck et al., *supra* note 19, at ch. 21, 273 (services covered and paid by Medicare “are limited to a short list of live video interactive services where an eligible Medicare beneficiary is located in a qualifying geographic location and facility (originating site) with extremely limited exceptions”); AM. MEDICAL ASS’N, REPORT 7-A-14 OF THE COUNCIL ON MEDICAL SERVICE, COVERAGE OF AND PAYMENT FOR TELEMEDICINE 2 (2014) (“narrow” list of covered services).

³¹ *See* 42 U.S.C. § 1395(m)(m)(4)(F).

³² *See* IFC, 85 Fed. Reg. at 19,232-41 (e.g., Emergency Department Visits; Initial and Subsequent Observation, and Observation Discharge Day Management; Initial Hospital Care and Hospital Discharge Day Management; Initial Nursing Facility Visits and Nursing Facility Discharge Day Management; Domiciliary, Rest Home, or Custodial Care Services; Home Visits; Inpatient Neonatal and Pediatric Critical Care; Initial and Continuing Intensive Care Services; Care Planning for Patients with Cognitive Impairment; Group Psychotherapy; End-Stage Renal Disease Services; Psychological and Neuropsychological Testing).

³³ *Id.* at 19,232-34 (describing “Category 1” services that are similar to the statutorily authorized telehealth services, and “Category 2” services that are not similar to the authorized services and require clinical studies to demonstrate whether the use of a telecommunications system to furnish the service benefits the patient). CMS established this non-statutory process for adding or deleting reimbursable telehealth services in 2002. *See* IFC, 85 Fed. Reg. at 19,233 (citing 67 Fed. Reg. 79,965, 79,988 (Dec. 31, 2002)); 42 C.F.R. § 410.78(f).

³⁴ *See id.* at 19,234 (CMS added to the list of payable services because the “use of telecommunication technology could mitigate the exposure risk, and in such cases, there is a clear clinical benefit of using such technology in furnishing the service . . . patients who should not be seen by a professional in-person due to the exposure risk are highly likely to be without access to clinically appropriate treatment or diagnostic options unless they have access to services furnished through interactive communication technology.”).

³⁵ *See, e.g.*, Judd E. Hollander & Brendan G. Carr, *supra* note 26; Jay Portnoy et al, *Telemedicine in the Era of COVID-19*, 8 J. ALLERGY CLIN. IMMUNOL. PRACT. 1489 (2020) (describing the use of telemedicine to avoid exposing non-COVID-19 patients and clinicians, and to assess and triage for COVID-19).

³⁶ Since CMS’s current procedures for authorizing telehealth services for reimbursement are not statutory, no statutory change should be necessary. *See supra* note 33. *See also* Sirina Keesara et al., *Covid-19 and Health Care’s Digital Revolution*, N. ENGL. J. MED. (Apr. 2, 2020), <https://www.nejm.org/doi/full/10.1056/NEJMp2005835> (information gained during the pandemic on whether new digital approaches increase clinical productivity “will be critical to understanding whether these emergency authorizations should be made permanent”).

³⁷ By statute, only physicians, physician assistants, nurse practitioners, clinical nurse specialists, nurse-midwives, clinical psychologists, clinical social workers, registered dietitians or nutrition professionals, and certified registered nurse anesthetists are eligible for reimbursement by Medicare for providing telehealth services. *See* 42 U.S.C. § 1395m(m)(4)(D), (E); 42 C.F.R. § 410.78(b)(2). *See also* Jonathan Linkous, *Overview of Common Challenges*, in INST. OF MED. OF THE NAT’L ACADEMIES, THE ROLE OF TELEHEALTH IN AN EVOLVING HEALTH CARE ENVIRONMENT: WORKSHOP SUMMARY 17, 18 (2012) (“another major barrier to the use of telemedicine is Section 1834(m) of the Social Security Act, which limits the use of telemedicine to certain providers.”).

³⁸ *See, e.g.*, Comment from FTC Staff to the Del. Bd. of Speech/Language Pathologists, Audiologists & Hearing Aid Dispensers, *supra* note 16, at 4-5 (discussing the range of speech and hearing care services that may be furnished via telehealth).

³⁹ *See, e.g.*, Trevor G. Russel & Deborah G. Theodoros, *Rehabilitation*, in UNDERSTANDING TELEHEALTH ch. 12, 155-56 (Karen S. Rheuban & Elizabeth A. Krupinski, eds., 2018). *See also* Steven C. Cramer et al., *Efficacy of*

Home-Based Telerehabilitation vs In-Clinic Therapy for Adults After Stroke: A Randomized Clinical Trial, 76 JAMA NEUROL. 1079, 1080 (2019) (telehealth provided by physical therapists and occupational therapists “is an effective means to provide rehabilitation therapy and improve patient outcomes after stroke and may be useful for improving access to rehabilitation therapy”).

⁴⁰ See IFC, 85 Fed. Reg. at 19,239-40.

⁴¹ See *id.* at 19,239 (90 percent of the time therapy services are furnished by therapy professionals, such as physical therapists, occupational therapists and speech-language pathologists).

⁴² See *id.* at 19,243-45 (“CTBS therapy services include those furnished to new or established patients that the occupational therapist, physical therapist, and speech-language pathologist practitioner is currently treating under a plan of care.”).

⁴³ See *id.* at 19,244-45 (these services can only be billed when there has not been a related service within the past 7 days and the service does not lead to a related service or procedure within the next 24 hours). See also Letter from Theresa H. Rodgers, President, American Speech-Language-Hearing Ass’n (“ASHA”), to Seema Verma, Administrator, CMS, Regarding CMS-1744-IFC, Apr. 3, 2020, at 2 (e-visits, virtual check-ins, and other forms of CTBS codes facilitate some interactions between patients and therapy providers, but “do not facilitate comprehensive evaluation and treatment, have limited practical utility, and do not extend access to services otherwise covered when provided in-person”).

⁴⁴ See CARES Act, Pub. L. 116-136, § 3703, 134 Stat. 416 (2020). Section 3703 of the CARES Act, *Increasing Medicare Telehealth Flexibilities during Emergency Period*, amends section 1135(b)(8) of the Social Security Act (42 U.S.C. § 1320b-5(b)(8)), so as to provide waiver authority pertaining to telehealth services “furnished in any emergency area . . . during any portion of any emergency period, the requirements of section 1834(m).” Section 1834(m) of the Social Security Act, 42 U.S.C. § 1395m(m), sets forth the requirements for Medicare reimbursement of telehealth services, including authorized providers.

⁴⁵ See CMS, COVID-19 EMERGENCY DECLARATION BLANKET WAIVERS FOR HEALTH CARE PROVIDERS (April 29, 2020), <https://www.cms.gov/files/document/summary-covid-19-emergency-declaration-waivers.pdf> (Flexibility for Medicare Telehealth Services, Eligible Practitioners).

⁴⁶ See, e.g., Alan Morgan, *National Rural Health Association*, in INST. OF MED. OF THE NAT’L ACADEMIES, THE ROLE OF TELEHEALTH IN AN EVOLVING HEALTH CARE ENVIRONMENT: WORKSHOP SUMMARY 115, 116 (2012) (recommending reimbursement of “care provided by physical therapists, respiratory therapists, and social workers. These services are in high demand in rural areas, but are often not available to rural communities.”). See also American Telemedicine Association, Comments to the Federal Trade Commission, Examining Health Care Competition 4 (April 30, 2015) (recommending reimbursement of “[p]rovider services otherwise covered by Medicare, such as physical therapy, occupational therapy and speech-language hearing services”); Alan Chong W. Lee & Nancy Harada, *Telehealth as a Means of Health Care Delivery for Physical Therapist Practice*, 92 PHYS. THER. 463, 463-464, 466 (2012) (physical therapists have used telehealth to deliver rehabilitative services to elderly individuals in their homes, but “Medicare poses the ultimate barrier to widespread telehealth implementation in the United States because physical therapists are not listed as eligible practitioners.”).

⁴⁷ See Comment from FTC Staff to the Del. Bd. of Speech/Language Pathologists, Audiologists & Hearing Aid Dispensers, *supra* note 16; Comment from FTC Staff to the Del. Bd. of Occupational Therapy Practice, *supra* note 16.

⁴⁸ See CMS, *supra* note 45 (audio-only telephone for certain services).

⁴⁹ See 42 C.F.R. § 410.78(a)(3) (For purposes of Medicare reimbursement, “[t]elephones, facsimile machines, and electronic mail systems do not meet the definition of an interactive telecommunications system.”). Medicare law does not specify the nature of the telecommunications system required for payment. See 42 U.S.C. § 1395m(m)(1) (“The Secretary shall pay for telehealth services that are furnished via a telecommunications system by a physician . . . or a practitioner . . . to an eligible telehealth individual enrolled under this part notwithstanding that the individual physician or practitioner providing the telehealth service is not at the same location as the beneficiary.”).

⁵⁰ See IFC, 85 Fed. Reg. at 19,243 (amending 42 C.F.R. § 410.78(a)(3) by adding (a)(3)(i), defining “interactive telecommunications system” for the duration of the PHE).

⁵¹ See, e.g., MONICA ANDERSON, MOBILE TECHNOLOGY AND HOME BROADBAND 2019 (June 13, 2019), <https://www.pewresearch.org/internet/2019/06/13/mobile-technology-and-home-broadband-2019/>; PEW RESEARCH CENTER, MOBILE FACT SHEET (June 12, 2019), <https://www.pewresearch.org/internet/fact-sheet/mobile/#mobile-phone-ownership-over-time>; ANDREW PERRIN, DIGITAL GAP BETWEEN RURAL AND NONRURAL AMERICA PERSISTS (May 31, 2019), <https://www.pewresearch.org/fact-tank/2019/05/31/digital-gap-between-rural-and-nonrural-america-persists/>; MONICA ANDERSON & MADHUMITHA KUMAR, DIGITAL DIVIDE PERSISTS EVEN AS LOWER-INCOME AMERICANS MAKE GAINS IN TECH ADOPTION (May 7, 2019), <https://www.pewresearch.org/fact-tank/2019/05/07/digital-divide-persists-even-as-lower-income-americans-make-gains-in-tech-adoption/>.

⁵² See Ateev Mehrotra et al., *Rapidly Converting to “Virtual Practices”: Outpatient Care in the Era of Covid-19*, 1 NEJM CATALYST: INNOVATIONS IN CARE DELIVERY (2020), <https://catalyst.nejm.org/doi/full/10.1056/CAT.20.0091>.

⁵³ See IFC, 85 Fed. Reg. at 19,265.

⁵⁴ See *id.* at 19,264-65 (codes for reimbursing telephone evaluation and management services provided by physicians and other professionals; codes for reimbursing telephone assessment and management services provided by nonphysicians).

⁵⁵ See *id.* at 19,265; *supra* note 43 and accompanying text. The IFC acknowledges the limited utility of the authorized CTBS, stating that under ordinary circumstances, patients requiring longer telephone evaluations would need an in-person or telehealth visit. See IFC, 85 Fed. Reg. at 19,265.

⁵⁶ See, e.g., Chethan Bachireddy et al., *Securing the Safety Net and Protecting Public Health During a Pandemic: Medicaid’s Response to COVID-19*, 323 JAMA 2009 (2020) (recommending that state Medicaid agencies should address technological barriers to telehealth by allowing clinicians and health care organizations to bill for telephonic services if they cannot provide the video component); Lori Uscher-Pines & Ateev Mehrotra, *Analysis of Teladoc Use Seems to Indicate Expanded Access to Care for Patients without Prior Connection to a Provider*, 33 HEALTH AFF. 258, 259 (2014).

⁵⁷ See IFC, 85 Fed. Reg. at 19,264 (current policy for CTBS non-telehealth services requires an established patient-practitioner relationship); *id.* at 19,244-45, 19,254, 19,264-65 (discussing non-face-to-face CTBS).

⁵⁸ See e.g., MEDICARE CLAIMS PROCESSING MANUAL ch 12, § 30.6.7.A (2019). Medicare defines an established patient as one who is not a “new patient,” which means “a patient who has not received any professional services, i.e., [evaluation and management] service or other face-to-face service (e.g., surgical procedure) from the physician or physician group practice (same physician specialty) within the previous 3 years.” *Id.* See also Am. Med. Ass’n, CPT Evaluation and Management (E/M) Office or Other Outpatient . . . and Prolonged Services . . . Code and Guideline Changes 9 (effective 2021, New and Established Patient), <https://www.ama-assn.org/system/files/2019-06/cpt-office-prolonged-svs-code-changes.pdf>; Jana Cason, *Telehealth is Face-to-Face Service Delivery*, 9 INT. J. TELEREHAB. 77 (2017) (“face-to-face” is an outmoded term that means “in person” care in Medicare and other regulations).

⁵⁹ See IFC, 85 Fed. Reg. at 19,244-45, 19,254, 19,264-65 (remote evaluation of recorded video, virtual check-in, online digital evaluation and management services, remote physiologic monitoring, telephone evaluation/management services). We also suggest that CMS clarify that the definition of “qualified providers,” which required physicians or other practitioners to have an established relationship with a patient for whom Medicare paid for a service furnished by the practitioner or another practitioner in the same practice within the previous three years, no longer applies because the CARES Act struck this definition of qualified provider on March 27, 2020. See *id.* at 19,251.

⁶⁰ *Id.* at 19,244.

⁶¹ See, e.g., Ateev Mehrotra et al., *The Dawn of Direct-to-Consumer Telehealth*, in UNDERSTANDING TELEHEALTH ch. 18, 217-18, 221 (Karen S. Rheuban & Elizabeth A. Krupinski, eds., 2018) (in DTC telehealth, the “clinician

typically does not have any established relationship with the patient, however, the patient will be matched to a clinician licensed to practice in his or her state of residence”).

⁶² See, e.g., Comment from FTC Staff to Paul Graves, *supra* note 16 (allowing eye care providers to decide whether to use telehealth); Comment from FTC Staff to the Del. Bd. of Speech/Language Pathologists, Audiologists & Hearing Aid Dispensers, *supra* note 16; Comment from FTC Staff to the Del. Bd. of Dietetics/Nutrition, *supra* note 16; Comment from FTC Staff to the Del. Bd. of Occupational Therapy Practice, *supra* note 16; Comment from FTC Staff to Steve Thompson, *supra* note 14 (allowing licensees located out-of-state to provide telehealth services without conducting an in person examination).

⁶³ See IFC, 85 Fed. Reg. at 19,245-46 (Under 42 C.F.R. § 410.26, “services incident to a physicians’ service usually require the direct supervision of a physician”). See also Social Security Act § 1861(s)(2)(A), 42 U.S.C. § 1395x(s)(2)(A) (services and supplies “furnished as an incident to a physician’s professional service, of kinds which are commonly furnished in physicians’ offices and are . . . included in the physicians’ bills); MEDICARE BENEFIT POLICY MANUAL, ch. 15, § 60, *Services and Supplies Furnished Incident to a Physician’s/NPP’s Professional Service* (July 12, 2019). Nonphysician practitioners “include, for example, certified nurse midwives, clinical psychologists, clinical social workers [“CSWs”], physician assistants, nurse practitioners, and clinical nurse specialists.” *Id.* at § 60.2.

⁶⁴ See 42 C.F.R. § 410.32(b)(3)(ii). Direct supervision “does not mean that the physician must be present in the room when the procedure is performed.” *Id.*

⁶⁵ See IFC, 85 Fed. Reg. at 19,246.

⁶⁶ See, e.g., Comment from FTC Staff to the Texas Medical Bd. 9 (Dec. 6, 2019), https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-comment-texas-medical-board-its-proposed-rule-19313-add-supervision-requirements-texas-certified/v200004_texas_nurse_anesthetists_advocacy_letter.pdf (discussing access problems in rural and underserved areas arising from supervision requirements for certified registered nurse anesthetists); FTC STAFF, POLICY PERSPECTIVES, *supra* note 9, at Sec.III (discussion of APRN physician supervision requirements). See also Barbara J. Safreit, *Federal Options for Maximizing the Value of Advanced Practice Nurses in Providing Quality, Cost-Effective Health Care*, in INST. OF MED. OF THE NAT’L ACADEMIES, THE FUTURE OF NURSING: LEADING CHANGE, ADVANCING HEALTH, App. H, 450 (2011) (in rural and underserved areas, patients are denied access to care provided by APRNs because of the lack of willing and available supervising physicians).

⁶⁷ See, e.g., Comment from FTC Staff to Valencia Seay, Senator, Ga. State Senate 3 (Jan. 29, 2016), https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-georgia-state-senator-valencia-seay-concerning-georgia-house-bill-684/160201gadentaladvocacy.pdf (regarding removal of direct supervision requirements for dental hygienists).

⁶⁸ See MEDICARE BENEFIT POLICY MANUAL, *supra* note 63, ch. 15, § 60.4(A); MEDICARE PAYMENT ADVISORY COMMISSION (“MEDPAC”), REPORT TO THE CONGRESS: MEDICARE AND THE HEALTH CARE DELIVERY SYSTEM 147 (June 2019) [hereinafter MEDPAC REPORT TO CONGRESS] (discussing how requiring direct supervision of nonphysician personnel for “incident to” billing restricted the provision of services by NPs and PAs in rural areas with few physicians).

⁶⁹ See MEDPAC REPORT TO CONGRESS, *supra* note 68, at 147; 42 U.S.C. § 1395x(s)(2)(K). The level of supervision required varies. For example, NPs and CNSs must collaborate with a physician to bill Medicare for their services. See 42 U.S.C. § 1395x(s)(2)(K)(ii); MEDICARE BENEFIT POLICY MANUAL, *supra* note 63, ch. 15, §§ 200, 210. General supervision is required for PAs, and may be provided by telephone. See 42 U.S.C. § 1395x(s)(2)(K)(i), MEDICARE BENEFIT POLICY MANUAL, *supra* note 63, ch. 15, § 190. Certified Nurse Midwives (“CNMs”) are not required to have a relationship with a physician for Medicare payment, and the level of supervision is set by state law. See MEDICARE BENEFIT POLICY MANUAL, *supra* note 63, ch. 15, § 180; 42 U.S.C. § 1395x(s)(2)(L).

⁷⁰ In 2016, about half of NPs likely had some or all of their services billed “incident to,” and about 43 percent of PAs. See MEDPAC REPORT TO CONGRESS, *supra* note 68, at 156, 157 (June 2019). It is not possible to precisely determine the extent of “incident to” billing because claims data do not show that a claim was billed “incident to,” and display the identifier of the billing physician, obscuring which practitioner provided care. See *id.* at 154-158.

⁷¹ See MEDPAC REPORT TO CONGRESS, *supra* note 68, at 128, 159, 167. See also 42 U.S.C. § 1395l(a)(1)(O) (for services directly billed by PAs, NPs, or CNSs under 42 U.S.C. § 1395x(s)(2)(K), “the amounts paid shall be equal to 80 percent of (i) the lesser of the actual charge or 85 percent of the fee schedule amount” for physicians). See also MEDICARE CLAIMS PROCESSING MANUAL, *supra* note 58, at ch. 12, §§ 110, 120. Direct payment rates vary, e.g., CNMs are paid 100% of the fee schedule amount for physicians regardless of whether billed directly or “incident to,” while CSWs who bill directly are paid 75% of the physician fee schedule amount. See 42 U.S.C. § 1395l(a)(1)(F), (K); MEDICARE CLAIMS PROCESSING MANUAL, *supra* note 58, at ch. 12, §§ 130, 150.

⁷² See MEDPAC REPORT TO CONGRESS, *supra* note 68, at 151, 155, 160 (June 2019).

⁷³ MEDICARE BENEFIT POLICY MANUAL, *supra* note 63, ch. 15, § 60.2.

⁷⁴ See Comment from FTC Staff to Valencia Seay, *supra* note 67, at 3.

⁷⁵ MEDPAC REPORT TO CONGRESS, *supra* note 68, at 159.

⁷⁶ We also note the difficulties with requiring audio/video telecommunications, discussed above in section II.D., and suggest that audio-only telecommunication be allowed for any supervision required by Medicare. This is consistent with Medicare requirements for general supervision. See *supra* note 69.

⁷⁷ Letter from Alexander M. Azar II, Secretary of Health and Human Services, to Governors 2 (Mar. 24, 2020), https://www.ncsbn.org/HHS_Secretary_Letter_to_States_Licensing_Waivers.pdf.

⁷⁸ Guidance to States 2 (Mar. 24, 2020), attachment to Letter from Alexander M. Azar II, *supra* note 77, https://www.ncsbn.org/HHS_Guidance_to_States_on_Regulations_on_Healthcare_Workers.pdf.

⁷⁹ Medicare Program: Changes to Hospital Outpatient . . . Payment . . . , 84 Fed. Reg. 61,142, 61,160 (Nov. 12, 2019).

⁸⁰ See, e.g., NAT’L CONF. OF STATE LEGISLATURES & ASS’N OF STATE AND TERRITORIAL HEALTH OFFICIALS, SCOPE OF PRACTICE POLICY, NURSE PRACTITIONER OVERVIEW, <http://scopeofpracticepolicy.org/practitioners/nurse-practitioners/> (last visited Feb. 10, 2020) (showing states with full independent practice authority, those for which a transition to independent practice period is required, and those requiring a physician relationship); AM. ASS’N OF NURSE PRACTITIONERS, 2019 NURSE PRACTITIONER STATE PRACTICE ENVIRONMENT (Dec. 20, 2018), <https://storage.aanp.org/www/documents/state-leg-reg/stateregulatorymap.pdf>; E. KATHLEEN ADAMS & SARA MARKOWITZ, THE HAMILTON PROJECT, IMPROVING EFFICIENCY IN THE HEALTH-CARE SYSTEM: REMOVING ANTICOMPETITIVE BARRIERS FOR ADVANCED PRACTICE REGISTERED NURSES AND PHYSICIAN ASSISTANTS, POLICY PROPOSAL 23-24 (June 2018), https://www.hamiltonproject.org/assets/files/AdamsandMarkowitz_20180611.pdf.

⁸¹ See, e.g., AM. ACAD. PAS (“AAPA”), THE SIX KEY ELEMENTS OF A MODERN PA PRACTICE ACT (June 2019), https://www.aapa.org/wp-content/uploads/2017/05/6_KE_Chart_5-5-17.pdf (chart of key PA practice provisions by state); AAPA, ISSUE BRIEF: THE SIX KEY ELEMENTS OF A MODERN PA PRACTICE ACT (Aug. 2018), <https://www.aapa.org/download/29342/>; E. KATHLEEN ADAMS & SARA MARKOWITZ, *supra* note 80 at 8-9, 22-3 (“Unlike APRNs, PAs must practice medicine under the supervision of a physician, but the required nature of that supervision varies by state. . . . Requirements may include collaborative work plans that outline the procedures the PA is allowed to perform and statements of required amount of physician contact, consulting, and monitoring.”); AM. MED. ASS’N, PHYSICIAN ASSISTANT SCOPE OF PRACTICE 2 (2018), <https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/public/arc-public/state-law-physician-assistant-scope-practice.pdf> (46 states and the District of Columbia require physician supervision of PAs, two states require collaboration agreements, and two allow for alternate arrangements).

⁸² States would have to allow remote supervision for practitioners to take advantage of a federal provision of this type. The March 24, 2020 letter from HHS Secretary Azar to state governors recommends that states, “Allow physicians to supervise a greater number of other health professionals and to do so using remote or telephonic means.” See Azar, *supra* note 77, at 1.

⁸³ See, e.g., MEDPAC REPORT TO CONGRESS, *supra* note 68, at 158; Emily A. Gadbois et al., *Trends in State Regulation of Nurse Practitioners and Physician Assistants, 2001 to 2010*, 72 MED. CARE RES. REV. 200 (2015).

⁸⁴ See CHOICE & COMPETITION REPORT, *supra* note 21, at 36 (The federal government and states should consider allowing “non-physician and non-dentist providers to be paid directly for their services where evidence supports that the provider can safely and effectively provide that care.”).

⁸⁵ See MEDPAC REPORT TO CONGRESS, *supra* note 68, at 160 (Recommendation 5-1, “The Congress should require advanced practice registered nurses and physician assistants to bill the Medicare program directly, eliminating ‘incident to’ billing for services they provide.”).

⁸⁶ See MEDPAC REPORT TO CONGRESS, *supra* note 68, at 159, 162. As explained above, Medicare direct billing rates vary by provider, ranging from 75 percent of the physician fee schedule rate to 100 percent. *See supra* note 71. Thus, eliminating “incident to” billing does not necessarily entail a change to a particular billing rate. We do not take a position on what billing rate is optimal for each type of nonphysician practitioner.