September 10, 2018

Submitted electronically via: http://regulations.gov/

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, D.C. 20201

Re: Comments on CY 2019 Medicare Physician Fee Schedule Proposed Rule (CMS-1693-P)

Dear Administrator Verma:

The Alliance for Connected Care ("the Alliance") welcomes the opportunity to provide feedback on the Centers for Medicare & Medicaid Services' ("CMS'") Medicare Physician Fee Schedule proposed rule, which updates the schedule for Calendar Year 2019 (CY19) and includes several important reforms with respect to telehealth and remote patient monitoring. We are grateful for your leadership in championing policies that will finally make virtual care an option for seniors, their caregivers and clinical providers.

The Alliance is a 501(c)(6) organization dedicated to creating a statutory and regulatory environment in which insurers and providers can deliver, and be adequately compensated for providing safe, high quality care using connected care technology. Our members are leading health care and technology companies from across the spectrum, representing insurers, health systems and technology innovators. The Alliance works in partnership with an Advisory Board of more than 20 patient and provider groups, including groups representing patients with chronic disease.

As reflected in the comments below, the Alliance is committed to leveraging telemedicine and remote patient monitoring to improve the quality of care while also lowering costs and improving efficiency. The Alliance applauds CMS' efforts to construct a creative workaround to the cumbersome telehealth restrictions included in Section 1834(m) of the Social Security Act ("the Act"). The Alliance also appreciates CMS' continued commitment to remote patient monitoring codes that will lead to this important technology becoming the standard of care for chronic disease.

Remote Patient Monitoring

In the proposed rule, CMS adds three new codes to the list of chronic care remote physiologic monitoring CPT codes reimbursable under Medicare: 990X0, which is a payment for initial set-up and patient education on use of monitoring equipment; 990X1, which is a per month payment for devices with daily recordings or programmed alert transmissions; and 994X9, which covers remote physiologic monitoring treatment services for twenty minutes or more per month by a physician, clinical staff, or other qualified health care professional. These three new remote patient monitoring codes will help bolster the existing 99091 remote patient monitoring code that CMS unbundled beginning on January 1, 2018.

The proposed rule also clarifies, through the new 994X9 code, that remote patient monitoring can be furnished by clinical staff. Explicitly including clinical staff in the code description eliminates any uncertainty that a clinic or health system may have about utilizing clinical staff with lower levels of training.

Members of the Alliance have found that remote patient monitoring services are best delivered by clinical staff under general supervision, as opposed to direct supervision. Direct supervision requires the physician to be in the same physical building at the same time as the clinical staff that is furnishing these services. This model is directly at odds with the objectives of remote patient monitoring. Aggregating clinical staff into a center of excellence with general supervision by the physician has proven to be the best model based on our members' results to date. Thus, we believe it is important for CMS to clearly state that these services may be furnished by clinical staff *under general supervision*. The Alliance also supports CMS' proposal to lower the time threshold for remote patient monitoring reimbursement to twenty minutes, compared to the thirty minutes that currently exists in the 99091 code.

As proposed, the remote patient monitoring codes and their respective relative value units (RVUs) adequately provide provision of these services, but do not leave any room for fee reductions. In practice, a $20 device setup (990X0) and an additional $122 per month for device and interactive communication services (990X1 plus 994X9), plus a possible $59 for complex patients (99091) would leave a very small margin for operation.

The Alliance has found that the most effective model for remote patient monitoring equipment deployments is through a package delivered to and recovered from the patient by a shipping entity (USPS, FedEx, UPS, etc.). This operation cannot be accomplished for $20 round-trip. Thus, we recommend raising the Initial Setup and Patient Education (990X0) code reimbursement to at least $100. With this increased reimbursement rate, providers would not have to take on financial risk on the initial deployment then subsequently recover that amount in monthly fees. The current competitive commercial market rate for such remote patient monitoring on-boarding fees is $140.

The Alliance strongly supports the inclusion of the new remote patient monitoring codes in the proposed rule and holds the belief that the additional codes will encourage providers to be more receptive to utilizing remote patient monitoring technologies to improve care quality and cost efficiency. However, increased reimbursement and general supervision are essential for the codes to be taken up at the rate needed to realize the full benefits of this technology.

Remote Evaluation of Pre-Recorded Patient Information

CMS is also proposing to add a new code (HCPCS code GRAS1 to describe "the remote professional evaluation of patient-transmitted information conducted via pre-recorded 'store and forward' video or image technology." The proposed rule clarifies that these services would not be subject to telehealth restrictions included in Section 1834(m) of the Act.

The proposal seeks comment on whether this service should be limited to established patients. The Alliance supports the denotation of an "established patient" as defined by the American Medical

Association (AMA) and the Federation of State Medical Boards (FSMB). Both of these organizations state that a provider-patient relationship can be established via a face-to-face visit, and that face-to-face visit may occur on a video telehealth platform. All fifty states have passed similar legislation. Thus, the Alliance supports allowing the patient and provider to establish their relationship during the same telehealth visit in which they are furnishing store and forward services. CMS should also clarify that clinicians in the same practice who cross-cover for their colleagues are deemed to have a relationship with the patient.

The proposed rule also specifies that images must be transmitted by the patient, which would exclude qualified health providers from being able to send images, videos, and scans to each other for the purposes of consult. Presently, very few patients have access to their health data, images, and scans for myriad reasons – for example, electronic health record platforms are oftentimes not user-facing, and such images and scans are large files that are not easily portable. Making the proposed store and forward code available for provider-to-provider use, rather than solely for patient-to-provider use, could have a substantially positive impact on patient care and utilize the technology to its fullest potential.

For example, a 2016 study published in the Journal of the American Academy of Dermatology looked at the impact of store and forward teledermatology between a primary care provider (PCP) and dermatologist in an underserved urban primary care setting. The study suggested that "teledermatology enhances the delivery of outpatient dermatologic care in the primary care setting" and that the use of store and forward practices in dermatology "increases the speed and accessibility of dermatologic consultation" by saving the patient a visit to their specialist's office.[1]

Additionally, CMS is proposing, based on RVUs in the proposed rule, that patient-initiated store and forward services would be reimbursed at about $14 per image or video transmitted, which is significantly lower than the current market rate of about $25. The Alliance believes that physicians would make better use of the store and forward tools available to them if Medicare reimbursement compares more closely to that of the private insurance market. We are concerned that commercial carriers will reduce their rates to match Medicare, thereby shrinking the number of providers willing to use technology that does not pay enough to cover their practice expenses. In addition, clinicians, particularly specialists, have special expertise that took years and significant resources to acquire. The length of time it takes them to evaluate a patient's need should not impact how much they are paid. In fact, the more expertise and experience, the shorter time it takes them to diagnose the issue. Using time as a measure of effort does not work well with remote technology. Practitioners should be reimbursed for their expertise.

Interprofessional Internet Consultations

CMS is proposing the addition of six new codes for the purpose of "interprofessional telephone/internet assessment and management service provided by a consultative physician including a verbal and written report to the patient's treating/requesting physician or other qualified health care professional." Two of

[1] Nelson CA, Takeshita J, Wanat KA, et al. Impact of store-and-forward (SAF) teledermatology on outpatient dermatologic care: A prospective study in an underserved urban primary care setting. J Am Acad Dermatol. 2016;74(3):484-90.e1. https://www.ncbi.nlm.nih.gov/pubmed/26679528

the codes pertain to the reimbursement of the treating provider who is requesting the consult; the other four apply to the consultative provider, which are on a time-based reimbursement scale.

The Alliance believes that knowledge and expertise in a professional field like medicine is extremely valuable, and reimbursement of these services should be valued as such. We are very pleased about CMS' initiative to enhance connectivity between providers for the benefit of the beneficiary. It is long overdue, and we appreciate your leadership.

The proposed rule mentions that the interprofessional internet consultations describe "services conducted through telephone, internet, or electronic health record consultations." The Alliance urges CMS to include secure messaging platforms in its definition of internet communication, since many providers face interoperability barriers when attempting to communicate via messaging systems embedded in electronic health record platforms.

Brief Non-Face-to-Face Communications-Based Visits ("Virtual Check-Ins")

While we greatly appreciate all of the steps taken to advance communications-based technologies, CMS' commitment to telehealth was most visible in the proposed language establishing reimbursement for virtual check-ins. We appreciate the time, effort and creativity that went into developing this new code that would reimburse for non-face-to-face communications-based visits, or "virtual check-ins," in light of very restrictive statutory limitations.

We are concerned, however, that CMS's virtual check-in proposal may not be aligned with its stated goal of "increas[ing] access for Medicare beneficiaries to physicians' services that are routinely furnished via communication technology…" The value of telehealth lies in treatment in a low-cost, accessible setting; follow-up care; and ongoing patient engagement. It is unclear whether the proposed virtual check-in may be used to address any of these three areas, and may instead simply pay for services physicians are already offering at no charge.

While the Preamble language makes clear that the codes were established for triage purposes, the regulatory impact analysis asserts that the codes "provide new options for physicians to treat patients." Using these codes as a mechanism for determining whether a patient needs to seek care in a brick-and-mortar setting would likely be duplicative to what many physician offices are already doing without payment. We are concerned that if this code is approved for triage, it may replace complimentary services, thereby driving up telehealth utilization without a subsequent decrease in other kinds of more expensive care, which misses the value of telehealth.

Using these codes for treatment would better reflect the true value of telehealth. However, as we mentioned above, we do not believe there are particular services that are uniquely virtual. Telehealth is medicine delivered through a different modality. If medical standards of care deem it safe to provide particular services virtually, it should not matter if they are delivered through telecommunications technology or in person. They are equally valuable. That is why we are working hard with Congress to lift the burdensome statutory restrictions that limit the use of telehealth in uses cases such as primary care and behavioral health. In the meantime, we understand you are doing what you can to make

telehealth available, but we fear that the creation of codes specific to telehealth will bifurcate telehealth and health care, which are one in the same with different modalities.

If CMS clarifies in the final rule that the virtual check-in codes can be used for treatment, we urge you to reconsider your determination that the use of this code requires "low work time and intensity." As discussed earlier, clinicians – including those who practice remotely – work very hard to develop expertise that is useful to patients. The length of time associated with a visit should not matter if the patient receives high quality treatment. Similar to our concern above, if CMS deems telehealth as taking less time or intensity, we risk undervaluing telehealth in the future when the statutory restrictions are lifted and seniors finally are able to visit a doctor through telehealth.

If CMS finalizes these codes without clarifying that they can be used for treatment, one way to capture more of the value of telehealth is to eliminate the bundling of in-person visits. Virtual visits are an excellent way to follow up with patients after an in-person visit. For example, a study published in Diabetes Care found that, among patients with diabetes-related foot ulcers who received follow up primary care, the telehealth group had a significantly lower proportion of amputations.[2] If CMS chooses not to expand the codes to treatment writ large, there would be greater value to patients and their providers if these codes could at least be used for follow up care.

As mentioned above, we believe that established patients should be defined by the guidelines of the American Medical Association and the Federation of State Medical Boards, which allow for a relationship to be established through a face-to-face virtual visit. We also urge CMS to clarify that cross-covering is permissible in determining established relationship.

Regarding the question embedded in the proposed rule about modality, we recommend that the definition of "communications technology-based service" be consistent with the definition of "telecommunications system" in section 1834(m). We are concerned about program integrity implications of allowing phone, text and email to be reimbursed as a virtual check-in.

In summary, we are very appreciative of your efforts to give seniors access to telehealth, but we have concerns with the structure of the virtual check-in, and hope that CMS will consider our comments. The difficulties of constructing policy around the outdated and overly burdensome restrictions of section 1834 cannot be overstated and this rule brings into stark relief how important it is for Congress to act. The 1834(m) restrictions must be lifted so CMS can craft appropriate policies that serve the best interests of patients and providers alike. Seniors should be able to see providers for E/M visits virtually. Telehealth is not a separate service; it is medicine delivered by a virtual modality. While the steps taken in the proposed rule represent significant progress, we will only be able to realize the true value of new technologies with congressional action.

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[2] Smith-Strom H, Igland J, et al. The Effect of Telemedicine Follow-up Care on Diabetes-Related Foot Ulcers: A Cluster-Randomized Controlled Noninferiority Trial. Diabetes Care 2018 Jan; 41(1): 96-103. https://doi.org/10.2337/dc17-1025

Thank you again for the opportunity to provide feedback on the CY19 Physician Fee Schedule rule. If you have any questions, please do not hesitate to contact us. I can be reached at krista.drobac@connectwithcare.org or 202-415-3260.

Sincerely,

Krista Drobac

Krista Drobac
Executive Director
Alliance for Connected Care