



December 28, 2020

Submitted electronically via: <https://www.regulations.gov>

Alex M. Azar, II
Secretary of the Department of Health and Human Services
U.S. Department of Health & Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: Regulatory Relief to Support Economic Recovery Request for Information

Dear Secretary Azar:

The American Gastroenterological Association (AGA) and the American Society for Gastrointestinal Endoscopy (ASGE) appreciate the opportunity to provide comments on the request for information (RFI), published in the *Federal Register* on November 25, 2020, regarding regulatory relief to support economic recovery. Together, our two societies represent the majority of all practicing gastroenterologists who provide preventive, consultative and therapeutic care for the U.S. population.

The RFI seeks to collect information for the purpose of considering the costs and benefits, consistent with applicable law and with protection of the public health and safety, of retaining certain regulatory changes beyond the COVID–19 public health emergency (PHE).

The Department of Health and Human Services (HHS) asked for feedback on the regulatory changes made in response to the COVID–19 PHE and the pandemic for each of the three categories regarding changes that:

- a. Have been beneficial to healthcare or human services providers, healthcare or human services systems, or to the patients and clients using these providers and systems, and under what circumstances; or
- b. Have been detrimental to healthcare or human services providers, healthcare or human services systems, or to the patients and clients using these providers and systems, and under what circumstances; or
- c. Have been beneficial to healthcare or human services providers, healthcare or human services systems, or to the patients and clients using these providers and systems on a temporary basis, but would be detrimental if continued, absent the exigencies of the COVID–19 PHE and pandemic. Please explain and provide any evidence you have of benefit or detriment.

Of the regulatory changes that have been made by the HHS in response to the COVID-19 PHE and the pandemic, HHS has asked commenters to identify which changes:

- a. Should be maintained only for the duration of the PHE and pandemic;
- b. Should be maintained after the expiration of the PHE or the end of the pandemic; i.e., made permanent;
- c. Should be extended for a period of time after the expiration of the PHE or the end of the pandemic without being made permanent;
- d. Should be modified but maintained after the expiration of the PHE or the end of the pandemic, and thus made permanent with modifications, and what modifications are being proposed; or
- e. Should be discontinued immediately.

In this letter we offer comments on the following areas:

- Telehealth
 - 4. Notification of Enforcement Discretion for Telehealth Remote Communications
 - 113. Telephone Evaluation and Management (E/M) Services Codes
 - 125. Payment for Medicare Telehealth Services Under Section 1834(m) of the Act
 - 149. Updating the Medicare Telehealth List on a Sub-regulatory Basis
 - 189. Allow Use of Audio-Only Equipment to Furnish Audio-Only Telephone E/M, Counseling, and Educational Services
 - 280. Medicare Advantage (MA) Cost-Sharing
 - 281. Telehealth
 - 291. MA and Part D Plan Flexibility to Waive Cost Sharing and to Provide Expanded Telehealth Benefits
- Prior Authorization
 - 226 and 285. Use of Prior Authorization
- Emergency Preparedness Policies and Procedures
 - 157. Waiver of Requirement to Develop and Implement Emergency Preparedness Policies and Procedures

Telehealth

4. Notification of Enforcement Discretion for Telehealth Remote Communications

HHS' instruction to allow enforcement discretion for telehealth remote communications has been beneficial to healthcare providers and patients on a temporary basis allowing them the flexibility needed to care for patients during the COVID-19 PHE. We applaud HHS for not imposing penalties for HIPAA violations against healthcare providers in connection with their good-faith provision of telehealth using remote communication technologies. We recommend the current flexibilities should be extended for one year after the expiration of the PHE or the end of the pandemic without being made permanent. We believe it will be important to review the rules for telehealth remote communications in place prior to the COVID-19 PHE and determine if

changes are needed to preserve flexibility for providers and patients while still maintaining appropriate HIPAA protections.

113. Telephone Evaluation and Management (E/M) Services Codes

Telephone E/M services have been beneficial to healthcare providers and patients and should be maintained (i.e., made permanent) after the expiration of the PHE or the end of the pandemic.

Telephone E/M services have been a lifeline for Medicare beneficiaries, many of whom do not have access to smart phones or internet for real-time video E/M visits, are not comfortable using the technology or do not have reliable internet or cell phone service.

During the COVID-19 pandemic, studies have been conducted that affirm the widespread anecdotal reports from physicians that many Medicare beneficiaries have difficulty with video visits and report satisfaction with the quality of E/M services provided via telephone and more studies are currently underway. We offer the following studies as evidence that telephone E/M is needed for the Medicare population and for underserved and minority populations.

A recent study, Positive Early Patient and Clinician Experience with Telemedicine in an Academic Gastroenterology Practice during the COVID-19 Pandemic¹, published in *Gastroenterology* describes a ‘real-world’ experience of patient- and clinician-rated acceptability of telephone and video outpatient visits during the initial four weeks of the emergency COVID-19 response at a large, diverse gastroenterology (GI/hepatology) practice in an academic health system. During the study period, a total of 1,718 patients had GI/hepatology visits; 104 (6%) were in person and 1614 (94%) were via telemedicine. Mean patient age was 60 (SD=16); 59% were female, 20% were Black, 64% White, and 16% Other/Unknown. In this early period, 27% of visits were conducted via video and 72% via telephone. In week 1, 7% of telemedicine visits were via video; this increased to 47% by week 4. After adjusting for study week and demographics, Black race (OR 2.6, 95% CI 1.6-4.2) and age 60+ (OR 1.9, 95% 1.4-2.7), were independently associated with having telephone versus video visits. There were notable racial and age differences in online portal use; 87% portal use among Whites versus 39% of Blacks; 77% among age <60 versus 48% among age 60+; P<.0001. A conclusion of the study was that practices should continue work to mitigate disparities in access to technology and low digital literacy. *The study highlights the importance of continued access to telephone E/M for patients age 60+ and Black patients who, according to the study, were less likely to be able to use video visit technology. It is important to maintain access to telephone E/M for these populations; failure to do so will further increase the racial disparities we have seen regarding both COVID-19 and colorectal cancer screening and uptake.*

¹ Serper M, Nunes F, Ahmad N, Roberts D, Metz DC, Mehta SJ, Positive Early Patient and Clinician Experience with Telemedicine in an Academic Gastroenterology Practice during the COVID-19 Pandemic, *Gastroenterology* (2020), doi: <https://doi.org/10.1053/j.gastro.2020.06.034>.

The study, *Assessing Telemedicine Unreadiness Among Older Adults in the United States During the COVID-19 Pandemic*², published in the *Journal of the American Medical Association* describes a cross-sectional study of community-dwelling adults (N = 4525) using 2018 data from the National Health and Aging Trends Study, which is nationally representative of Medicare beneficiaries aged 65 or older, to assess the prevalence of telemedicine unreadiness. *The study estimates that 13 million older adults may have trouble accessing telemedical services; a disproportionate number of those may be among the already disadvantaged. Its conclusion was telephone visits may improve access for the estimated 6.3 million older adults who are inexperienced with technology or have visual impairment.*

A narrative review on "Telemedicine, the Current COVID-19 Pandemic, and the Future,"³ in *Family Medicine and Community Health* describes how telemedicine may also facilitate access to care, especially among rural and underserved populations, and reduce healthcare costs by decreasing emergency room visits and hospital admissions among patients with chronic illnesses. *The study finds that having more frequent communication with a patient who has a chronic condition can help them avoid readmissions to the hospital and emergency department, lowering the overall cost of chronic disease management.*

We agree with the Centers for Medicare and Medicaid Services (CMS) that in the context of the PHE and with the goal of reducing exposure risks associated with the COVID-19 pandemic, especially in cases where Medicare beneficiaries are unable or unwilling to use two-way, audio and video technology, there are circumstances where prolonged, audio-only communication between the practitioner and the patient can be clinically appropriate. However, the need for appropriate coverage and reimbursement of telephone E/M will not end on the date the PHE is declared over. Access to telephone E/M will continue to be necessary for at least one year after the year the PHE is declared to be over.

While we appreciate that CMS, in the 2021 Medicare Physician Fee Schedule Final Rule, created a new Healthcare Common Procedure Coding System (HCPCS) code (G2252) to capture extended services delivered via synchronous communications technology, including audio-only (e.g., virtual check-ins), we note that code G2252 is a communication technology-based service (CTBS) and is subject to all the other requirements of CTBS and we would argue that it is not the same as telephone E/M.

G2252 (Brief communication technology-based service, e.g. virtual check-in, by a physician or other qualified health care professional who can report evaluation and management services, provided to an established patient, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or

² Lam K, Lu AD, Shi Y, Covinsky KE. Assessing Telemedicine Unreadiness Among Older Adults in the United States During the COVID-19 Pandemic. *JAMA Intern Med.* Published online August 03, 2020. doi:10.1001/jamainternmed.2020.2671

³ Kichloo A, Albosta M, Dettloff K, et al. Telemedicine, the current COVID-19 pandemic and the future: a narrative review and perspectives moving forward in the USA. *Fam Med Community Health.* 2020;8(3):e000530. doi:10.1136/fmch-2020-000530

procedure within the next 24 hours or soonest available appointment; 11-20 minutes of medical discussion.)

In our comments on the 2021 MPFS proposed rule, we urged CMS to continue to cover and reimburse telephone E/M codes 99441-99443 at the rate established in the March 31, 2020 COVID-19 IFC (99441, 0.48 work relative value units (wRVU); 99442, 0.97 wRVU; 99443, 1.50 wRVU) until the telephone E/M codes are updated by the CPT Editorial Panel and valued by the Relative Value Scale (RVS) Update Committee (RUC), reviewed by CMS and published in an MPFS proposed rule for public comment.

We strongly disagree with CMS' new HCPCS code G2252. We argue that telephone E/M is clinically necessary for patients who cannot, either because of limited access to the necessary internet bandwidth to conduct a video visit, no availability to a smart phone or not being comfortable with or able to conduct a video visit. In its "Final Policy, Payment, and Quality Provisions Changes to the Medicare Physician Fee Schedule for Calendar Year 2019"⁴ fact sheet released November 1, 2018, CMS describes virtual check-in as a "brief communication technology-based service when the patient checks in with the practitioner via telephone or other telecommunications device to decide whether an office visit or other service is needed." Virtual check-ins of any duration are completely different from telephone E/M. Telephone E/M is not just a longer virtual check-in service, it is an E/M service.

For these reasons, we urge HHS to maintain (i.e., make permanent) beneficiaries' access to telephone E/M codes 99441-99443 at the current rates paid during the COVID-19 PHE after the expiration of the PHE or the end of the pandemic.

125. Payment for Medicare Telehealth Services Under Section 1834(m) of the Act

Telehealth services that have been added on an interim basis and changes that have been made eliminating frequency limitations and other requirements associated with particular services furnished via telehealth have been beneficial to healthcare providers and patients and should be maintained (i.e., made permanent) after the expiration of the PHE or the end of the pandemic.

We urge you to add telephone E/M codes 99441-99443 to the list of telehealth services at the current rates equivalent to in-person E/M services for the reasons stated in the section above.

149. Updating the Medicare Telehealth List on a Sub-regulatory Basis

We agree with HHS that the process established for adding or deleting services from the Medicare telehealth services list under regulation at § 410.78(f) to allow for an expedited process during the PHE that does not involve notice and comment rulemaking should be modified, and we agree with the plan as outlined. We appreciate HHS will consider adding services to the Medicare telehealth list on a sub-regulatory basis by posting new services to the web listing of telehealth services when the agency receives a request to add (or identifies through internal review) a service that can be furnished in full, as described by the relevant code, by a distant site practitioner to a beneficiary in a manner that is similar to the in-person service.

⁴ <https://www.cms.gov/newsroom/fact-sheets/final-policy-payment-and-quality-provisions-changes-medicare-physician-fee-schedule-calendar-year>

189. Allow Use of Audio-Only Equipment to Furnish Audio-Only Telephone E/M, Counseling, and Educational Services

Allowing use of audio-only equipment to furnish audio-only telephone E/M has been beneficial to healthcare providers and patients and should be maintained (i.e., made permanent) after the expiration of the PHE or the end of the pandemic. Pursuant to authority granted under the CARES Act, CMS is waiving the requirements of section 1834(m)(1) of the ACT and 42 CFR § 410.78(a)(3) for use of interactive telecommunications systems to furnish telehealth services, to the extent they require use of video technology, for certain services. This waiver allows the use of audio-only equipment to furnish services described by the codes for audio-only telephone E/M services, and behavioral health counseling and educational services, including office/outpatient new and established patient E/M codes 99201-99205 and 99211-99215. For the reasons stated in section “113. Telephone Evaluation and Management (E/M) Services Codes” of this comment letter, we urge HHS to make permanent coverage and reimbursement of audio-only (i.e., telephone E/M) at the rates of equivalent in-person E/M codes.

280. Medicare Advantage Cost-Sharing.

Medicare Advantage Organizations’ (MAOs) ability to waive or reduce enrollee cost-sharing for beneficiaries enrolled in their Medicare Advantage plans impacted by the outbreak has been beneficial to patients and should be maintained only for the duration of the PHE and pandemic.

The flexibility HHS has given to MAO’s to waive or reduce enrollee cost-sharing for COVID–19 treatment, telehealth benefits or other services to address the outbreak provided that the MAOs waive or reduce cost-sharing for all similarly situated plan enrollees on a uniform basis has been an important support for patients and has encouraged them to continue vital care during the PHE. We support HHS Office of Inspector General’s (OIG) advice that MAOs that voluntarily waive or reduce enrollee cost-sharing, as approved by CMS, would satisfy the safe harbor to the Federal anti-kickback statute set forth at 42 CFR 1001.952(l).

281. Telehealth

The flexibility CMS has given MAOs to expand coverage of telehealth benefits, as approved by CMS, has been beneficial to patients and medical providers and should be maintained (i.e., made permanent) after the expiration of the PHE or the end of the pandemic.

It would be disruptive to both clinical practice and beneficiary access to abruptly eliminate Medicare payment for telehealth services as soon as the PHE ends. Updating the Medicare Telehealth list on a sub-regulatory basis is an important step and will allow the opportunity to use information from studies conducted during the PHE to support requests for permanent changes to the Medicare telehealth services list.

During the PHE we learned it is often challenging to establish a synchronous telemedicine connection defined as "live, two-way audiovisual link between a patient and a care provider" with patients. We acknowledge certain circumstances necessitate an in-person interaction to determine the current health status of the patient; however, for established patients, clinical decision-making and care planning is well-informed based on the existing relationship and information documented in the medical record; therefore, we continue to advocate for telephone E/M to be an available and fully reimbursed option for those patients who need it. In our

comments on the 2021 MPFS proposed rule, we encouraged CMS to make permanent the communication flexibilities put into place during the PHE, in particular, allowing coverage and reimbursement for audio-only E/M for Medicare beneficiaries.

Prior Authorization

226 and 285. Use of Prior Authorization Flexibilities by Medicare Advantage Organizations

The flexibility MAOs have to waive or relax health plan prior authorization requirements during the PHE is a benefit to patients and medical providers, and CMS should continue to encourage MAOs after the expiration of the PHE or the end of the pandemic. However, permanent and meaningful reforms are needed.

Gastroenterologists care for patients with disorders of the bowel for which the use of biologics may constitute the primary treatment. Oftentimes, these biologics are administered in the physician's office and reimbursed under Part B. Prior authorization, as well as step therapy protocols, are problematic generally, and the pandemic has only emphasized the administrative burden of these utilization control mechanisms on physician practices and the ill-effects they have on patients.

For example, this July, in the midst of the pandemic, a payer made changes to its coverage of an anti-inflammatory biologic for a patient with persistent intestinal mucosal disease. This patient was in remission on low therapeutic levels of the biologic every seven weeks. The insurance company decided it was only going to cover the biologic every eight weeks. As a result, the physician had to appeal that decision and go through a peer-to-peer process. The appeal was denied by a physician with a different specialty background and with no experience with this biologic or condition. The appeal was denied because the patient had not had an office visit in 11 months, an absurd decision during a pandemic when physician practices are struggling to maintain normal levels of operation and patients have delayed seeking medical care. The case required a secondary appeal and led to a delay of care.

Consistent with bipartisan legislation — the *Improving Seniors' Timely Access to Care Act of 2019* (H.R. 3107) — introduced in the House during the 116th Congress and supported by our societies, CMS should streamline and standardize prior authorization processes within the Medicare Advantage program.

As captured in the above referenced legislation, these reforms should include:

- creation of an electronic prior authorization program including the electronic transmission of prior authorization requests and responses and a real-time process for items and services that are routinely approved;
- a requirement that Medicare Advantage plans report to CMS on the extent of their use of prior authorization and the rate of approvals or denials;

- a requirement that plans adopt transparent prior authorization programs that are reviewed annually, adhere to evidence-based medical guidelines, and include continuity of care for individuals transitioning between coverage policies to minimize any disruption in care;
- health plan accountability for making timely prior authorization determinations and providing rationales for denials; and
- prohibition of additional prior authorization for medically necessary services performed during a surgical or invasive procedure that already received, or did not initially require, prior authorization.

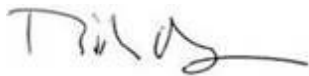
Emergency Preparedness Policies and Procedures

157. Waiver of Requirement to Develop and Implement Emergency Preparedness Policies and Procedures

As set forth in 42 CFR § 482.15(b) and § 485.625(b), hospitals and critical access hospitals (CAH), respectively, must develop and implement emergency preparedness policies and procedures which must be reviewed and updated at least every two years. Ambulatory surgery centers (ASCs) should be granted the same waiver of requirements as set forth in 42 CFR § 416.54 through the duration of the PHE and for a period of time after the expiration of the PHE. Extending to ASCs a waiver of requirement to develop and implement emergency preparedness policies and procedures will allow ASCs to focus already strained staff resources on COVID transmission mitigation efforts. Ensuring the waiver is in place for a period of time after the PHE ends will ensure ASCs have sufficient time following the PHE to meet requirements for emergency preparedness policies and procedures if their required two-year update occurs during the PHE.

The AGA and ASGE appreciate the opportunity to provide comments on the Regulatory Relief to Support Economic Recovery RFI. If we may provide any additional information, please contact Kathleen Teixeira, AGA, at 240-482-3222 or kteixeira@gastro.org; or Lakitia Mayo, ASGE, at 630-570-5641 or lmayo@asge.org.

Sincerely,



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