September 7, 2021

Center for Medicaid and Medicare Services (CMS)
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Ave. SW Washington, D.C. 20201

Re: RIN 0938–AU42, CY 2022 Revisions to Payment Policies under the Physician Fee Schedule (PFS) and Other Changes to Part B Payment Policies (Docket Number CMS-1751-P)

Submitted Electronically at Regulations.Gov

To Whom it May Concern:

We appreciate the opportunity to comment on the Department of Health and Human Services (HHS) Center for Medicaid and Medicare Services (CMS) CY 2022 Revisions to Payment Policies under the Physician Fee Schedule (PFS) and Other Changes to Part B Payment Policies Proposed Rule.

The Academy of Medicine of Cleveland & Northern Ohio (AMCNO), founded in 1824, is the region's professional medical association, and the oldest professional association in Ohio. We are a non-profit 501(c)6 representing over 5,000 physicians and medical students from Northern Ohio. The mission of the Academy of Medicine of Cleveland & Northern Ohio is to support physicians in being strong advocates for all patients and promote the practice of the highest quality of medicine.

CY 2022 Rate Setting and Conversion Factor

We support the ask of the American Medical Association (AMA) to extend the waiver of the budget neutrality adjustment considering the continued COVID-19 public health emergency. In this time of increased pressure on physician practices and hospitals, we simply cannot afford a payment reduction of 3.75 percent. In accordance with this stance, we oppose the proposed 2022 PFS conversion factor of $33.58 a decrease of $1.31 from CY 2021, as well as the proposed anesthesia conversion factor of $21.04, a decrease of $0.52 from CY 2021.

6111 Oak Tree Blvd., Ste 150
Cleveland, Ohio 44131
Tel: 216.520.1000
Fax: 216.520.0999
academyofmed@amcno.org
www.amcno.org

Comment Solicitation for Impact of Infectious Disease on Codes and Ratesetting

We appreciate CMS asking for provider feedback on additional costs borne by physicians due to the COVID-19 pandemic. We along with the AMA, urge CMS to implement and pay for CPT Code 99072, defined as additional supplies, materials and clinical staff over time over and above those usually included in an office visit or other non-facility service, when performed during a Public Health Emergency, as defined by law, due to respiratory-transmitted infectious disease, to compensate practices for the additional staffing and personal protection equipment (PPE) and other supplies needed during the COVID-19 pandemic, without passing those costs on to our patients.

Telehealth

We support CMS in proposing to continue paying for services intially placed temporarily on the telehealth list through the end of 2023. Telehealth is a critical part of the future of medicine and can help solve access problems for our patients. As we've seen during the COVID-19 pandemic, telehealth visits can be a necessary way to deliver care to patients when normal delivery of care is either unavailable or unattainable for a patient.

Telehealth visits during COVID-19 allowed physicians to continue managing patient care while protecting patient safety. We have also found that this convenient way of communicating with our patients results in both provider and patient satisfaction.

We applaud the work of CMS in allowing for the expansion of telehealth during the pandemic and we support the efforts continuing these expansions.

We also support CMS in proposing changes to remove geographic restrictions and permit home as an originating site. Again, as we saw during the pandemic, telehealth allowed patients critical access to their physicians, many of whom were following guidelines to stay at home, as long as the practitioner has seen the patient in person within the last 6 months.

CMS asked for feedback on whether this in-person requirement could apply to another physician or practitioner of the same specialty within the same practice group. We strongly support this change. Again, telehealth has an incredible opportunity to expand access, and the in-person requirements

threaten to hinder that access. By allowing more flexibility in being seen by another practitioner in the same practice, it ensures more patients will be able to utilize this necessary method of care.
During the Public Health Emergency (PHE), CMS allowed flexibility in the requirement for direct supervision for diagnostic tests, physician services, and some hospital outpatient services using virtual presence using real-time audio/video technology, instead of requiring a physician's physical presence. CMS asked for comment as to whether this flexibility should extend beyond the PHE. We strongly support this flexibility being made permanent. As technology continues to expand, providers will leverage the ability to provide assistance and supervision virtually where and when it is safe to do so.

Modifications Related to Medicare Coverage for Opioid Use Disorder (OUD) Treatment Services Furnished by Opioid Treatment Programs (OTPs)

In the proposed rule, CMS discusses allowing the use of two-way interactive audio/video communication technology, as clinically appropriate, to furnish the counseling and therapy portions of the weekly bundle of services and additional counseling or therapy services furnished by OTPs. Due to the Public Health Emergency (PHE) for COVID– 19, in the interim final rule with comment period (IFC) entitled "Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency," CMS revised § 410.67(b)(3) and (4) to allow the therapy and counseling portions of the weekly bundles, and any additional counseling or therapy, to be furnished using audio-only telephone calls rather than via two-way interactive audio/video communication technology for the duration of the PHE for COVID-19.

Under the policy adopted in the March 31, 2020, COVID-19 IFC, counseling and therapy could be furnished using audio-only telephone calls only where two-way audio/video communications technology is not available to the beneficiary, and provided all other applicable requirements were met. CMS believed this change was necessary to ensure that beneficiaries with opioid use disorders would be able to continue to receive these important services during the PHE during which the public has been instructed to practice self-isolation or social distancing, and because interactive audio/video communication technology may not be available to all beneficiaries. CMS is now proposing making permanent this flexibility in response to the public comments and other stakeholder feedback that using audio-only telephone calls to furnish therapy and counseling in cases where two-way audio/video communication technology is not available to the beneficiary after the end of the PHE for the COVID-19 pandemic would facilitate broader access to services. We strongly support this policy change to ensure

continued access to care to those beneficiaries enrolled in OTPs. We also recommend that the agency not require additional documentation in the medical record supporting audio-only services, if this is the only way patient can receive care additional documentation is duplicative and unnecessary.

We also support CMS in establishing a payment methodology for the 8mg naloxone hydrochloride nasal spray product recently approved by the FDA. This change is welcome and helpful. Often the 4mg product is not enough to reverse an overdose and reimbursing the 8mg kit will reduce the per-overdose costs of administering naloxone.

Innovative Technology and Artificial Intelligence (AI) Request for Information (RFI)

In the proposed rule, CMS solicited feedback on a variety of questions regarding coverage of AI and other innovative technologies. Please see our answers and comments below.

- To what extent are innovative technologies like software or AI are replacing physician work?

  AI is constantly evolving, and the extent in which AI may be replacing physician work or adding to physician work is not known at this time. There are no large studies to show that AI has replaced physician work in a meaningful and reproducible way.

- How innovative technology such as software algorithms and/or AI is affecting physician work time and intensity of furnishing services involving the use of such technology?

  In some instances, physician work has changed, and it is important to understand that physician work does not occur in a vacuum in which one factor offsets another. For example, the promise of electronic health records was to make physician work more efficient. However, there are a number of large studies which have shown that electronic health records have actually increased physician work to the point of significantly contributing to physician burn-out due to the workload burden imposed by electronic health records.[1] There is also a large study showing that there was significant bias in studies reporting on the improved performance of AI compared

[1] (Gardner RL, Cooper E, Haskell J, Harris DA, Poplau S, Kroth PJ, Linzer M.J. Physician stress and burnout: the impact of health information technology. Am Med Inform Assoc. 2019 Feb 1;26(2):106-114

with physicians which may indicate that AI is not ready to be implemented in a widespread fashion.[2] For tasks where a machine has surpassed human performance (e.g., screening cancer, diabetic retinopathy, and certain heart conditions), or for situations where human doctors are unavailable, but a machine can do a good job (e.g., using a chatbot to show a patient how to give an insulin injection), complete AI automation is possible. The key, however, in human-machine partnership is to keep the delicate balance between the types of care that are needed and the levels of automation that AI technologies offer. In very few instances, physician work is reduced, but it is too early to know if AI will reliably reduce physician work in most other areas.

- How is innovative technology such as software algorithms and/or AI changing cost structures in the physician office setting?

  Current software algorithms and AI are associated with high acquisition costs. In the current predominant pay-for-performance model that CMS has in place, these costs may not translate into improved profit in the physician office setting. For example, the current cost of the AI program for detection of colon polyps during screening colonoscopy would add $15 - $60 to each procedure cost which is not reimbursed. On the other hand, the detection of more adenomatous polyps in a screening colonoscopy could lead to increased revenue downstream for a particular physician office setting. This increased yield in removing colon polyps, however, would lead to lower overall costs to CMS by reducing the number of colon cancers needing to be treated.[3]

[2] (Nagendran M, Chen Y, Lovejoy CA, Gordon AC, Komorowski M, Harvey H, Topol EJ, Ioannidis JPA, Collins GS, Maruthappu M. Artificial intelligence versus clinicians: systematic review of design, reporting standards, and claims of deep learning studies. BMJ. 2020 Mar 25;368:m689

[3] Spadaccini M, Iannone A, Maselli R, Badalamenti M, Desai M, Chandrasekar VT, Patel HK, Fugazza A, Pellegatta G, Galtieri PA, Lollo G, Carrara S, Anderloni A, Rex DK, Savevski V, Wallace MB, Bhandari P, Roesch T, Gralnek IM, Sharma P, Hassan C, Repici A. Computer-aided detection versus advanced imaging for detection of colorectal neoplasia: a systematic review and network meta-analysis. Lancet Gastroenterol Hepatol. 2021 Aug 4:S2468-1253(21)00215-6)

- How is innovative technology affecting beneficiary access to Medicare-covered services?

  AI is constantly evolving, and the extent in which AI may or may not affect beneficiary access to Medicare-covered services is not known at this time. There are no large studies to show that AI has resulted in easier or harder access to these services. It is possible that AI will result in more personalized medicine for patients that will lead to better-informed decisions for treatment, but for now these are services which Medicare does not cover. For example, the use of AI in diabetic retinopathy management has resulted in proposed treatment regimens that Medicare does not cover, which then results in a beneficiary not being able to access that care.

Thank you again for the opportunity to comment.

Sincerely,

Kristin Englund, MD, MLS
President, the Academy of Medicine of Cleveland & Northern Ohio